

EXHIBIT 6



June 2018

DRUG DISCOUNT PROGRAM

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

Why GAO Did This Study

Covered entities can provide 340B drugs to eligible patients and generate revenue by receiving reimbursement from patients' insurance. The number of pharmacies covered entities have contracted with has increased from about 1,300 in 2010 to nearly 20,000 in 2017. GAO was asked to provide information on the use of contract pharmacies. Among other things, this report: 1) describes financial arrangements selected covered entities have with contract pharmacies; 2) describes the extent that selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and 3) examines HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies. GAO selected and reviewed a nongeneralizable sample of 30 contracts between covered entities and pharmacies, 20 HRSA audit files, and 55 covered entities to obtain variation in the types of entities and other factors. GAO also interviewed officials from HRSA and 10 covered entities.

What GAO Recommends

GAO is making seven recommendations, including that HRSA's audits assess for duplicate discounts in Medicaid managed care, and HRSA require information on how entities determined the scope of noncompliance and evidence of corrective action prior to closing audits. HHS agreed with four of the recommendations, but disagreed with three recommendations, which GAO continues to believe are warranted to improve HRSA's oversight as explained in the report.

View [GAO-18-480](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

DRUG DISCOUNT PROGRAM

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

What GAO Found

The 340B Drug Pricing Program (340B Program), which is administered by the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), requires drug manufacturers to sell outpatient drugs at a discount to covered entities so that their drugs can be covered by Medicaid. Covered entities include certain hospitals and federal grantees (such as federally qualified health centers). About one-third of the more than 12,000 covered entities contract with outside pharmacies—contract pharmacies—to dispense drugs on their behalf. GAO's review of 30 contracts found that all but one contract included provisions for the covered entity to pay the contract pharmacy a flat fee for each eligible prescription. The flat fees generally ranged from \$6 to \$15 per prescription, but varied by several factors, including the type of drug or patient's insurance status. Some covered entities also agreed to pay pharmacies a percentage of revenue generated by each prescription.

Thirty of the 55 covered entities GAO reviewed reported providing low-income, uninsured patients discounts on 340B drugs at some or all of their contract pharmacies. Of the 30 covered entities that provided discounts, 23 indicated that they pass on the full 340B discount to patients, resulting in patients paying the 340B price or less for drugs. Additionally, 14 of the 30 covered entities said they determined patients' eligibility for discounts based on whether their income was below a specified level, 11 reported providing discounts to all patients, and 5 determined eligibility for discounts on a case-by-case basis.

GAO found weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies, such as:

- HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, manufacturers cannot be required to provide both the 340B discount and a rebate through the Medicaid Drug Rebate Program. However, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care. As a result, it cannot ensure compliance with this requirement for the majority of Medicaid prescriptions, which occur under managed care.
- HRSA requires covered entities that have noncompliance issues identified during an audit to assess the full extent of noncompliance. However, because HRSA does not require all the covered entities to explain the methodology they used for determining the extent of the noncompliance, it does not know the scope of the assessments and whether they are effective at identifying the full extent of noncompliance.
- HRSA does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing the audit. Instead, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity came into compliance with 340B Program requirements.

Given these weaknesses, HRSA does not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements.

Contents

Letter		1
	Background	6
	About One-Third of Covered Entities Had One or More Contract Pharmacies, and Pharmacy Characteristics Varied	16
	Selected Covered Entities Used Various Methods to Pay Contract Pharmacies and TPAs	24
	About Half of the Covered Entities Reviewed Provided Low-Income, Uninsured Patients Discounts on 340B Drugs at Some or All of Their Contract Pharmacies	30
	Oversight Weaknesses Impede HRSA's Ability to Ensure Compliance at 340B Contract Pharmacies	35
	Conclusions	44
	Recommendations for Executive Action	46
	Agency Comments and Our Evaluation	46
Appendix I	Summary of Fees Included in 340B Pharmacy Contracts Reviewed	51
Appendix II	Comments from the Department of Health and Human Services	55
Appendix III	GAO Contacts and Staff Acknowledgments	62
Tables		
	Table 1: Health Resources and Services Administration's (HRSA) Definition of a Patient Eligible for Discounted Drugs under the 340B Program	10
	Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), by Fiscal Year	15
	Table 3: Distance (in Miles) between Covered Entities and Their Contract Pharmacies as of July 1, 2017, by Entity Type	23
	Table 4: Examples of Methods Used by 39 Covered Entities to Pay Third-Party Administrators (TPA) for Reviewing and Processing 340B Prescriptions	29
	Table 5: Income Thresholds Used by Selected Covered Entities to Determine Eligibility for 340B Discounts, by Entity Type	34

Table 6: Examples of Methods Used by 30 Covered Entities to Inform Contract Pharmacies of Patients' Eligibility for Discounts	35
Table 7: Summary of Health Resources and Services Administration's (HRSA) Audit Findings Related to Contract Pharmacies, as of February 8, 2018	38
Table 8: Fees That 30 Selected Covered Entities Pay to Contract Pharmacies for Dispensing 340B Drugs, by Entity Type	51

Figures

Figure 1: Types of Entities Eligible to Participate in the 340B Program	8
Figure 2: Illustrative Example of a 340B Program Contract Pharmacy Arrangement	12
Figure 3: Example of How Covered Entities, Contract Pharmacies, and Third-Party Administrators Work Together to Dispense 340B Drugs	14
Figure 4: Percent of Covered Entities That Had at Least One Contract Pharmacy as of July 1, 2017, by Entity Type	17
Figure 5: Distribution of Contract Pharmacies as of July 1, 2017, by Covered Entity Type	19
Figure 6: Percent of 340B Program Contract Pharmacies by Pharmacy and Covered Entity Type, as of July 1, 2017	22
Figure 7: Percent of Covered Entities with Contract Pharmacies within Given Distances as of July 1, 2017, by Entity Type	24
Figure 8: Types of Fees Included in Selected Contracts between Covered Entities and Pharmacies, by Entity Type	25
Figure 9: Number of Selected Covered Entities that Reported Providing Discounts to Low-Income, Uninsured Patients on the Price of 340B Drugs Dispensed at Contract Pharmacies, by Entity Type	31
Figure 10: Prices Patients Pay for 340B Drugs for 30 Covered Entities That Reported Providing Discounts at Their Contract Pharmacies, by Entity Type	32
Figure 11: Number of Selected Covered Entities That Reported Providing Discounts on Dispensing and Administrative Fees at Contract Pharmacies, by Entity Type	33

Abbreviations

CMS	Centers for Medicare & Medicaid Services
FQHC	federally qualified health center
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
TPA	third-party administrator

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



June 21, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
House of Representatives

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The 340B Drug Pricing Program (340B Program), named for the statutory provision authorizing it in the Public Health Service Act, requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—certain hospitals and recipients of federal grants—to have their drugs covered by Medicaid.¹ According to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program, the purpose of the 340B Program is to enable covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.² In 2017, there were more than 12,000 covered entities and more than 38,000 total sites participating in the 340B Program.

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to HRSA. In addition, covered entities can generate revenue as they can purchase 340B drugs for eligible patients whose insurance

¹42 U.S.C. § 256b. Medicaid is a joint federal-state program that finances health care, including prescription drugs, for certain low-income and medically needy populations.

²HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the Public Health Service Act. See H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). See also Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act).

reimbursement exceeds the 340B price paid for the drugs. The statute authorizing the 340B Program does not dictate how covered entities should use this revenue or require discounts on the drugs to be passed along to patients. Incentives for participation by drug manufacturers are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs.

A covered entity typically purchases and dispenses 340B drugs through pharmacies—either through an in-house pharmacy; through the use of a contract pharmacy arrangement, in which the entity contracts with an outside pharmacy and pays it to dispense drugs on its behalf; or both. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance, and in March 2010, HRSA issued final guidance allowing covered entities to have an unlimited number of contract pharmacies.³ Since that time, the number of contract pharmacies has increased significantly, from about 1,300 at the beginning of 2010 to around 20,000 in 2017.

Covered entities are required to meet certain conditions set forth both in law and interpretive agency guidance.⁴ For example, they are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.⁵ They are also prohibited from subjecting manufacturers to “duplicate discounts” in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.⁶ Covered entities that use contract pharmacies are responsible for overseeing those pharmacies to ensure compliance with 340B Program prohibitions on drug diversion and duplicate discounts. Some covered entities hire and pay a private company, referred to as a third-party administrator (TPA), to help determine patient eligibility and manage 340B inventory as a means to ensure compliance with 340B Program requirements at contract pharmacies.

³Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).

⁴Since the establishment of the 340B Program, HRSA has used interpretive guidance and statements of policy to provide guidance to covered entities regarding compliance with program requirements, including statutory prohibitions on duplicate discounts and diversion. See, for example, 75 Fed. Reg. 10273 (Mar. 5, 2010).

⁵42 U.S.C. § 256b(a)(5)(B).

⁶42 U.S.C. § 256b(a)(5)(A).

In a September 2011 report, we identified inadequacies in HRSA's oversight of the 340B Program and recommended ways for HRSA to improve oversight and ensure appropriate use of the program.⁷ In response, HRSA has taken action to improve its oversight of covered entities, including implementing a systematic approach to conducting audits of covered entities.⁸ Given the growth in the 340B Program, there has been continued interest in program oversight, and how the increase in contract pharmacies affects the integrity of the program. You asked us to review the use of contract pharmacies in the 340B Program. In this report we

1. describe the extent to which covered entities contract with pharmacies to distribute 340B drugs, and characteristics of these pharmacies;
2. describe financial arrangements selected covered entities have with contract pharmacies and TPAs related to the administration and dispensing of 340B drugs;
3. describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and
4. examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies.

To examine the extent to which covered entities contract with pharmacies to distribute 340B drugs and the characteristics of these pharmacies, we analyzed HRSA's 340B Program database to identify the covered entities registered to participate in the 340B Program and the contract pharmacies registered to dispense 340B drugs for each entity, as of July 1, 2017—the most current data available when we began our analysis.⁹ The pharmacy characteristics we reviewed included the type of pharmacy and the distance between the pharmacy and the covered entities with which it had a contract. To determine the types of pharmacies that participated as contract pharmacies, we matched the pharmacies included in the 340B database with data from the National Council for

⁷See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, [GAO-11-836](#) (Washington, D.C.: Sept. 23, 2011).

⁸See GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight*, [GAO-17-749T](#) (Washington, D.C.: July 18, 2017).

⁹According to the data we received from HRSA, at the time of our analysis, there were more than 12,000 covered entities registered to participate in the 340B Program.

Prescription Drug Programs' DataQ—a database used by health care payers and claims processors across the country to identify pharmacies, which contains information reported by pharmacies on their pharmacy type and ownership, among other items.¹⁰ We used the addresses included in the 340B database to determine the location of each covered entity, its affiliated sites, and its contract pharmacies and used this information to determine the distance between the entity and its contract pharmacies.¹¹ We calculated the distance (in miles) from the pharmacy to the nearest site of the covered entity. To assess the reliability of the 340B and DataQ databases, we obtained information from officials who are knowledgeable about them regarding steps taken to ensure the accuracy of the information contained in each, and performed checks to identify missing or incorrect data. Based on these steps, we determined that the data were sufficiently reliable for the purposes of our reporting objective.

To describe financial arrangements selected covered entities have with contract pharmacies and TPAs, we reviewed a sample of contracts between entities and pharmacies and collected information from selected entities and TPAs. We selected a nongeneralizable sample of 30 pharmacy contracts from among those that HRSA had collected—contracts the agency obtained during audits of covered entities from fiscal years 2014 through 2016.¹² We selected contracts to obtain variation in the type of covered entity (15 hospitals and 15 federal grantees) and geographic location. For these selected contracts, we identified the types and amounts of fees that covered entities agreed to pay contract pharmacies for dispensing and managing 340B prescriptions, as well as

¹⁰We matched the contract pharmacies in the 340B database to DataQ using the pharmacy's Drug Enforcement Agency number, which is a unique identifier used for tracking prescribers of controlled substances. About 1 percent of the 340B contract pharmacies (162 pharmacies) did not have a Drug Enforcement Agency number in the 340B database, and an additional 2 percent of the 340B contract pharmacies (405 pharmacies) for which a number was available in the 340B database did not have a corresponding record in DataQ, and thus their pharmacy types are unknown.

¹¹We excluded 26 contract pharmacies that categorized themselves as mail order pharmacies from our distance calculations. In addition, we also excluded 103 covered entities (less than 3 percent of entities with contract pharmacies) and 644 contract pharmacies (about 3 percent of contract pharmacies) from our distance analysis because we were unable to determine their physical locations based on their addresses.

¹²HRSA collects copies of contracts between covered entities and their contract pharmacies as part of its audit process. Fiscal years 2014 through 2016 were the most recent period for which HRSA completed audits, and thus, the most recent time period of contracts HRSA had on file at the time we began our analysis.

determined factors that may have impacted the fee amounts. To describe financial arrangements covered entities have with TPAs, beginning in September 2017, we sent a data collection instrument—which we refer to as a questionnaire in this report—to a nongeneralizable sample of 60 covered entities that had contract pharmacies to obtain information about the arrangements they had with TPAs.¹³ We received responses from 55 of the covered entities—28 hospitals and 27 federal grantees. In addition, we interviewed 10 of the 55 covered entities that responded to our questionnaire to obtain more detailed information about the fees they pay their TPAs. We selected covered entities to receive the questionnaire and for interviews to achieve variation in terms of their type, geographic location, and number of contract pharmacies. Finally, we interviewed two TPAs to gain insights about the types of financial arrangements they have with covered entities.

To describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients, we used the same questionnaire as previously noted to collect information about any discounts provided. This included information on the proportion of pharmacies at which discounts on 340B drugs were available, how covered entities determined which patients were eligible for those discounts, the prices these patients generally paid to obtain the drugs, and how covered entities inform patients and contract pharmacies about the availability of discounts. Additionally, we asked officials from the 10 covered entities we interviewed for additional information about discounts provided on 340B drugs dispensed to low-income, uninsured patients at contract pharmacies.

To examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies, we reviewed relevant policies, procedures, and guidance, including HRSA's 2010 guidance on contract pharmacy services and documentation of the agency's audit procedures. We also analyzed summaries of HRSA's audits of covered entities for fiscal years 2012 through 2017, posted on its website as of February 8,

¹³Four covered entities that received our questionnaire informed us that although they had contract pharmacies registered in HRSA's 340B database, they did not use them and thus, would not be able to answer our questionnaire. As a result, we sent the questionnaire to four additional covered entities.

2018.¹⁴ We conducted an in-depth review of a nongeneralizable sample of 20 audits that were conducted from fiscal years 2014 through 2016 for covered entities that had contract pharmacies at the time of the audit.¹⁵ We selected this sample from among audits that were closed by HRSA to obtain variation in terms of covered entity type and audit findings.¹⁶ We also interviewed HRSA officials about their oversight activities, including their audit process, and spoke with the contractor that has conducted audits on HRSA's behalf since fiscal year 2017.¹⁷ Additionally, we asked officials from the 10 covered entities interviewed about their practices for overseeing contract pharmacies. Finally, we evaluated HRSA's contract pharmacy guidance, covered entity oversight, and audit process against federal internal control standards related to control activities, information and communication, and monitoring.¹⁸

We conducted this performance audit from January 2017 to June 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives 340B covered entities discounts on outpatient drugs comparable to those made available to

¹⁴As of that date, audit results were available for all audits conducted through fiscal year 2016 and 169 of the 200 audits conducted in fiscal year 2017.

¹⁵At the time we began our review, fiscal year 2017 audits were ongoing, so we reviewed selected audits from the prior three years.

¹⁶If the audit contains findings, HRSA closes the audit once the covered entity attests that all required corrective actions to address the findings have been addressed and any necessary repayments have been made to affected manufacturers.

¹⁷Beginning in fiscal year 2017, HRSA contracted with The Bizzell Group to perform the audits on its behalf. The Bizzell Group provides a completed audit protocol to HRSA, which the agency then uses to determine the audit findings and issue a final audit report. HRSA spent \$3.8 million in fiscal year 2017 for 340B Program audit services.

¹⁸See GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

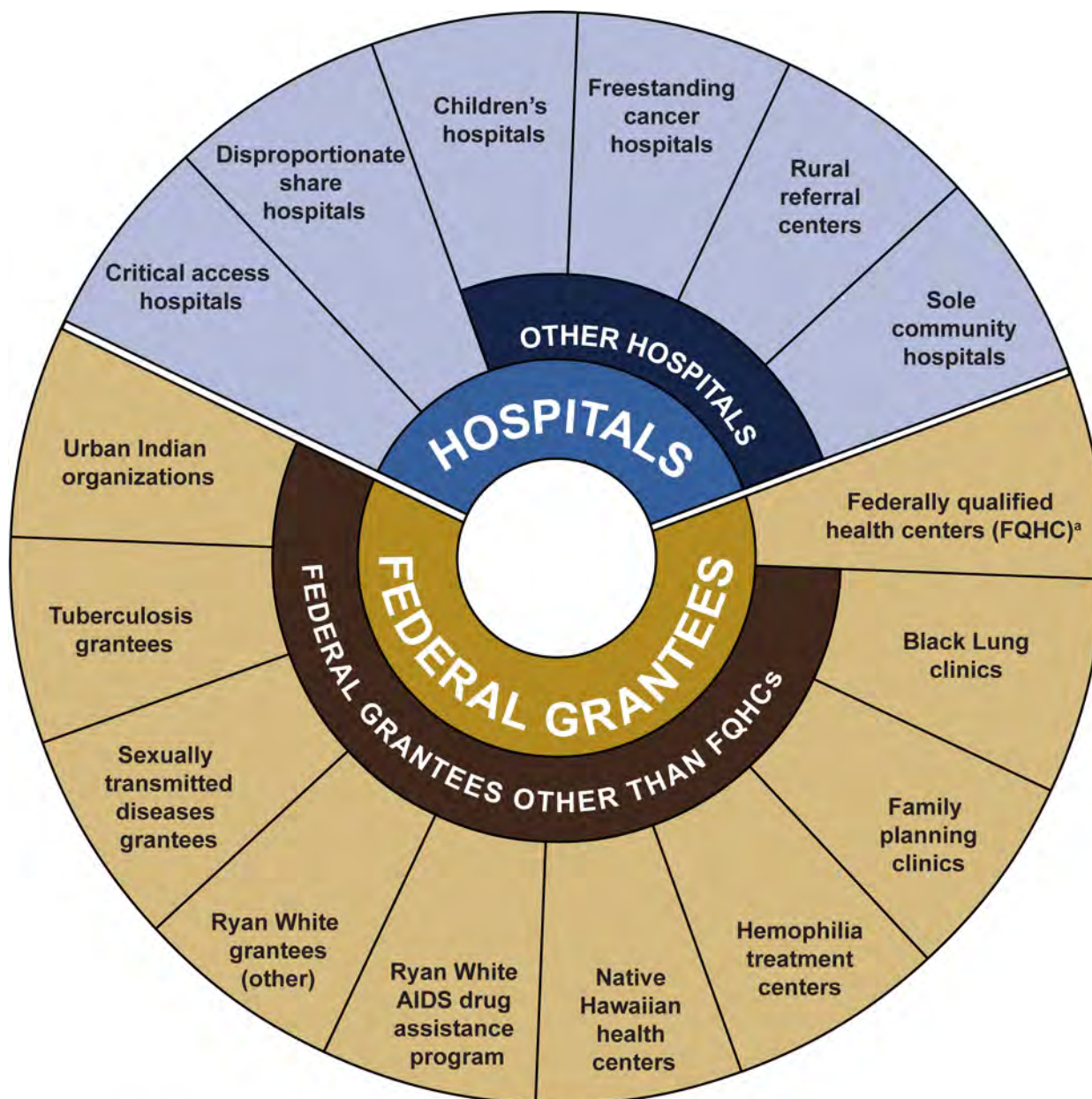
state Medicaid agencies.¹⁹ HRSA is responsible for administering and overseeing the 340B Program.

340B Program Eligibility

Eligibility for the 340B Program, which is defined in the Public Health Service Act, has expanded over time. Covered entities generally become eligible for the 340B Program by qualifying as certain federal grantees or as one of six specified types of hospitals. Eligible federal grantees include federally qualified health centers (FQHCs), which provide comprehensive community-based primary and preventive care services to medically underserved populations, as well as certain other federal grantees, such as family planning clinics and Ryan White HIV/AIDS program grantees. Eligible hospitals include critical access hospitals—small, rural hospitals with no more than 25 inpatient beds; disproportionate share hospitals—general acute care hospitals that serve a disproportionate number of low-income patients; and four other types of hospitals (see fig. 1).

¹⁹The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding Social Security Act § 1927; codified as amended at 42 U.S.C. § 1396r-8).

Figure 1: Types of Entities Eligible to Participate in the 340B Program



Source: GAO analysis of section 340B of the Public Health Service Act. | GAO-18-480

^aNot all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program, but do not receive federal grants, are referred to as FQHC look-alikes and are eligible to participate in the 340B Program.

Some covered entities, typically hospitals and FQHCs, have multiple sites: the main site, which HRSA refers to as the parent site, and one or more other associated sites referred to as child sites. Child sites can include satellite clinics, off-site outpatient facilities, hospital departments, and other facilities. According to HRSA officials, to participate in the 340B Program and be considered part of the covered entity, the associated sites must meet program requirements and be registered with HRSA as a child site.

Program Structure, Operation, and Key Requirements

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a participating drug manufacturer may charge covered entities.²⁰ Covered entities must follow certain requirements as a condition of participating in the 340B Program. For example, covered entities are prohibited from

- subjecting manufacturers to “duplicate discounts” in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.²¹
- diverting any drug purchased at the 340B price to an individual who is not a patient of the covered entity. Under HRSA guidance defining this term, diversion generally occurs when 340B drugs are given to individuals who are not receiving health care services from covered entities or are receiving services that are not consistent with the type of services for which the covered entity qualified for 340B status. (See table 1 for more information on HRSA’s definition of an eligible patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the 340B Program definition of a patient regardless of their financial or insurance status.

²⁰Manufacturers may sell a drug at a price that is lower than the ceiling price. As such, covered entities may negotiate prices below the ceiling price.

²¹The Patient Protection and Affordable Care Act expanded the Medicaid Drug Rebate Program to include drugs dispensed to Medicaid beneficiaries through managed care plans. Pub. L. No. 111-148, § 2501(c)(1), 124 Stat. 119, 308 (2010). Prior to the effective date of this expansion (Mar. 23, 2010), manufacturers’ responsibility to pay Medicaid rebates for outpatient drugs covered was limited to drugs covered under Medicaid fee-for-service.

Table 1: Health Resources and Services Administration’s (HRSA) Definition of a Patient Eligible for Discounted Drugs under the 340B Program

Criteria for patient eligibility ^a
1. The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual’s health care.
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity. ^b
3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or federally qualified health center look-alike status has been provided. ^c

Source: GAO analysis of HRSA guidance. | GAO-18-480

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B Program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

^aThese criteria do not apply to Ryan White AIDS drug assistance programs, which serve as a “payer of last resort” to cover the cost of providing HIV-related medications to certain low-income individuals. Rather an individual enrolled in a Ryan White AIDS drug assistance program is considered a patient of the covered entity if registered as such by the state program.

^bAn individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

^cAccording to HRSA, hospitals are exempt from this requirement. Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the health center program, but do not receive federal grants, are referred to as look-alikes and are eligible to participate in the 340B Program.

Contract Pharmacies

Covered entities may choose to dispense 340B drugs they purchase through contract pharmacies. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance. HRSA’s original guidance permitting the use of contract pharmacies limited their use to entities that did not have in-house pharmacies and allowed each entity to contract with only one outside pharmacy.²² However, March 2010 guidance lifted the restriction on the number of pharmacies with which a covered entity could contract.²³ Since that time, the number of contract pharmacies has increased more than fifteen-fold, from about 1,300 to approximately 20,000. According to HRSA guidance, a covered entity is required to have a written contract in place with each pharmacy through which it intends to dispense 340B drugs, but is not

²²See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43551, 43555 (Aug. 23, 1996).

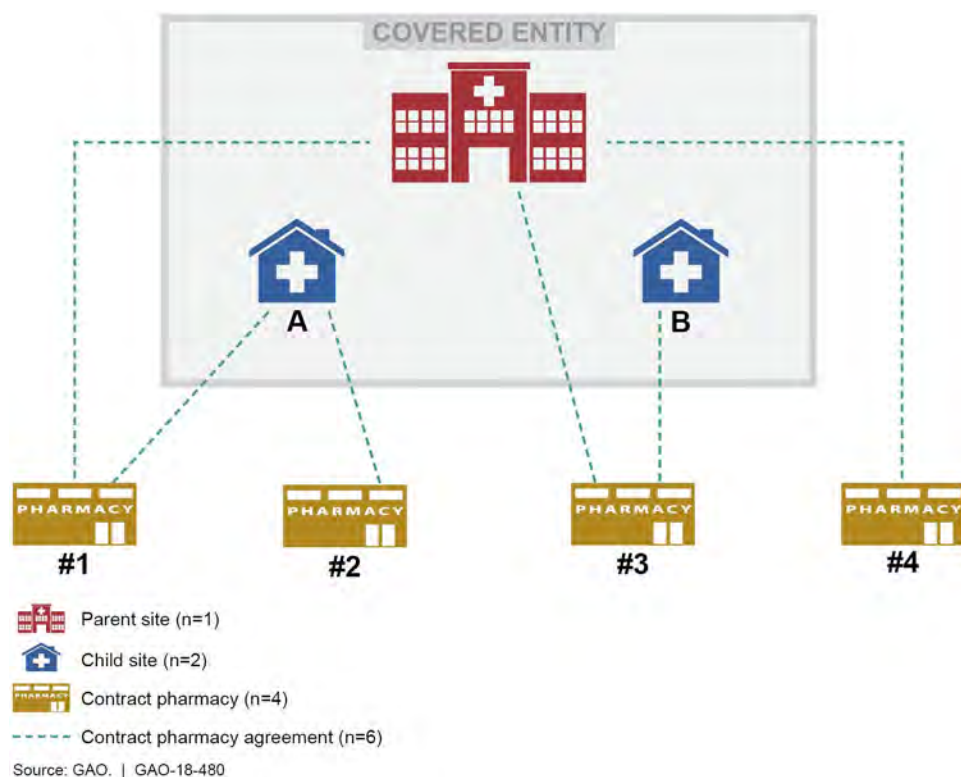
²³See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272, 10277 (Mar. 5, 2010).

generally required to submit its pharmacy contracts to HRSA.²⁴ A covered entity that has more than one site at which it provides health care may enter into separate pharmacy contracts for the parent site and each child site, or one comprehensive pharmacy contract including all sites intending to use the pharmacy.²⁵ It is up to the covered entity to determine which of its sites will be included in a contract with a pharmacy, and thus have what is referred to as a contract pharmacy arrangement with that pharmacy. Figure 2 provides an illustration of a covered entity that has four contract pharmacies but a total of six contract pharmacy arrangements, as not all of the entity's sites have contracts with each of the pharmacies.

²⁴HRSA's guidance specifies that contracts must be provided to HRSA upon request. HRSA obtains copies of a small number of covered entities' pharmacy contracts. Specifically, HRSA collects contracts for covered entities that are audited, and in fiscal year 2017, began collecting contracts for 5 percent of new pharmacy registrations.

²⁵Similarly, a contract can include multiple pharmacies from the same company, or a covered entity could have a separate contract with each pharmacy.

Figure 2: Illustrative Example of a 340B Program Contract Pharmacy Arrangement



Covered entities that choose to have contract pharmacies are required to register with HRSA the names of each of the pharmacies with which they contract. Covered entities may register their contract pharmacies in one of two ways: 1) only in relation to the parent site (use by child sites would be allowed as long as the sites were included in a comprehensive contract between the entity and the contracted pharmacies); or 2) separately for each site (parent and child) involved in a contractual arrangement with the pharmacy. As part of this registration, HRSA guidance specifies that covered entities must certify that they have signed and have in effect an agreement with each contract pharmacy and have a

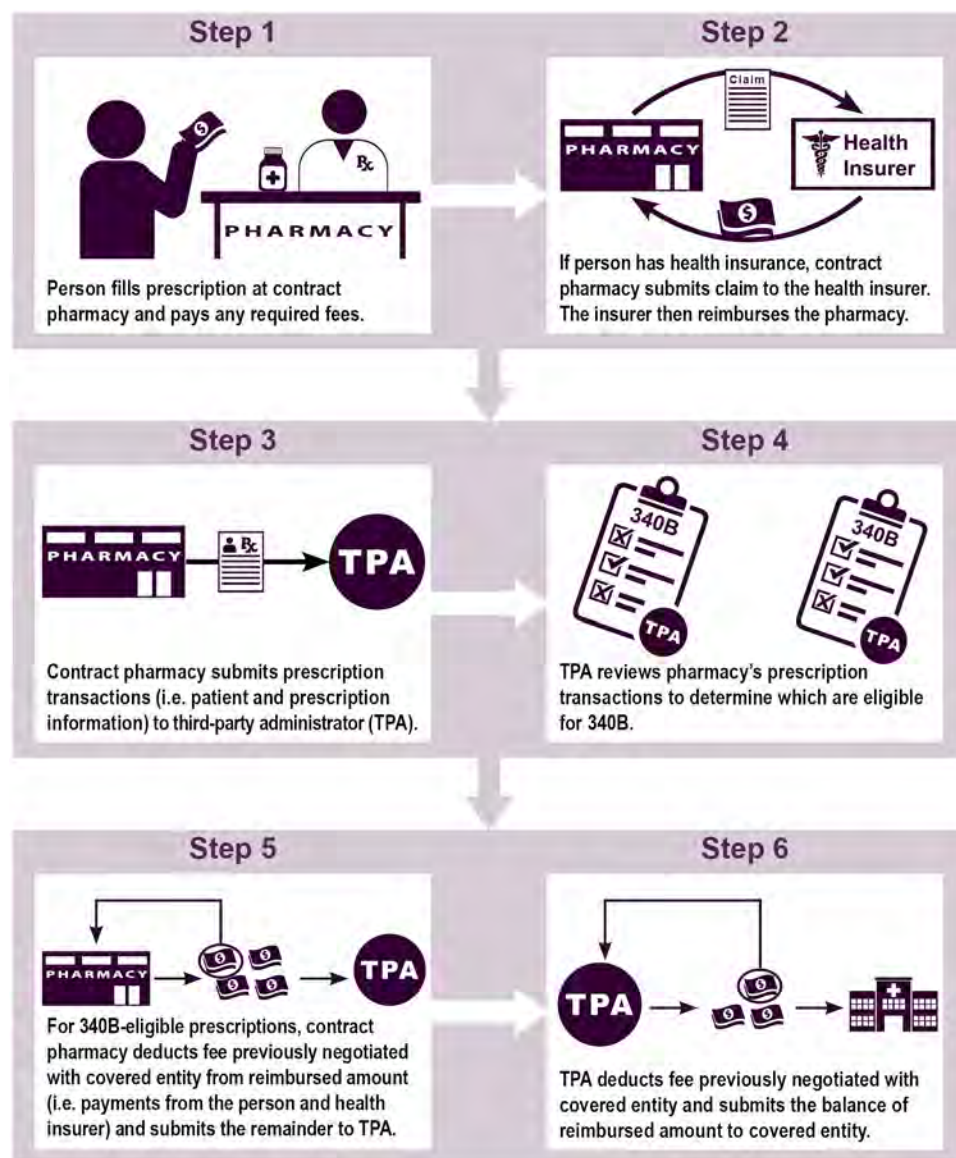
plan to ensure compliance with the statutory prohibitions on 340B drug diversion and duplicate discounts at their contract pharmacies.²⁶

Like other pharmacies, when contract pharmacies fill prescriptions, they collect payments from the patient; if the patient has health insurance, the pharmacy will bill the insurer for the drug. In addition, each covered entity must determine which prescriptions are for eligible patients of the entity, and thus, can be filled with 340B drugs. One way that a covered entity could choose to do this is to employ a TPA to review all the prescriptions filled by a contract pharmacy to determine which, if any, prescriptions were issued by the covered entity to an eligible patient, and thus are eligible for the 340B discount. The covered entity then pays both the contract pharmacy and the TPA fees that they have negotiated for their roles in managing and distributing 340B drugs.²⁷ These fees are typically deducted from the reimbursed amounts received from patients and their health insurers by the pharmacy and TPA, and then the balance is forwarded to the covered entity. (See fig. 3 for an example of how covered entities work with contract pharmacies and TPAs to dispense 340B drugs.)

²⁶For a contract pharmacy to dispense 340B drugs to patients covered under Medicaid fee-for-service, HRSA guidance requires that the covered entity, the contract pharmacy, and the state Medicaid agency have an agreement in place to prevent duplicate discounts and report the agreement to HRSA. 75 Fed. Reg. 10278 (Mar. 5, 2010).

²⁷The 340B Program statute does not impose any requirements or limitations on the fees that covered entities may pay their contract pharmacies or TPAs.

Figure 3: Example of How Covered Entities, Contract Pharmacies, and Third-Party Administrators Work Together to Dispense 340B Drugs



Source: GAO. | GAO-18-480

Note: Not all covered entities employ a TPA to help manage the dispensing of 340B drugs at contract pharmacies; entities that do not may have their own staff perform the TPA duties depicted in the illustration.

HRSA's Oversight of Covered Entities

In fiscal year 2012, HRSA implemented a systematic approach to conducting audits of covered entities that is outlined on its website. HRSA has increased the number of covered entities audited since it began audits in fiscal year 2012, and now audits 200 entities per year. (See table 2.) HRSA's audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year), and covered entities that are targeted based on information from stakeholders such as drug manufacturers (10 percent of the audits conducted).²⁸ The criteria for risk-based audits include a covered entity's volume of 340B drug purchases, number of contract pharmacies, time in the 340B Program, complexity of its program, and history of violations or allegations of noncompliance associated with diversion and duplicate discounts.

Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), by Fiscal Year

Fiscal year	Number of audits	Percent of covered entities audited ^a
2012	51	0.5
2013	94	0.9
2014	99	0.9
2015	200	1.7
2016	200	1.7
2017	200	1.6

Source: GAO analysis of HRSA data. | GAO-18-480

^aDetermined using the number of covered entities as of January 1 of each fiscal year.

Among other things, HRSA's audits include reviews of each covered entity's policies and procedures, including those for overseeing contract pharmacies; an assessment of the entity's compliance with respect to 340B eligibility status, the prevention of duplicate discounts and diversion, and other program requirements; and reviews of a sample of prescriptions filled during a 6-month period, including prescriptions dispensed by contract pharmacies, to identify instances of non-compliance. As a result of the audits conducted, HRSA has identified instances of non-compliance with program requirements, including violations related to drug diversion and the potential for duplicate

²⁸Targeted audits also include covered entities selected for a follow-up audit by HRSA as a result of findings from a prior audit. These are referred to as re-audits.

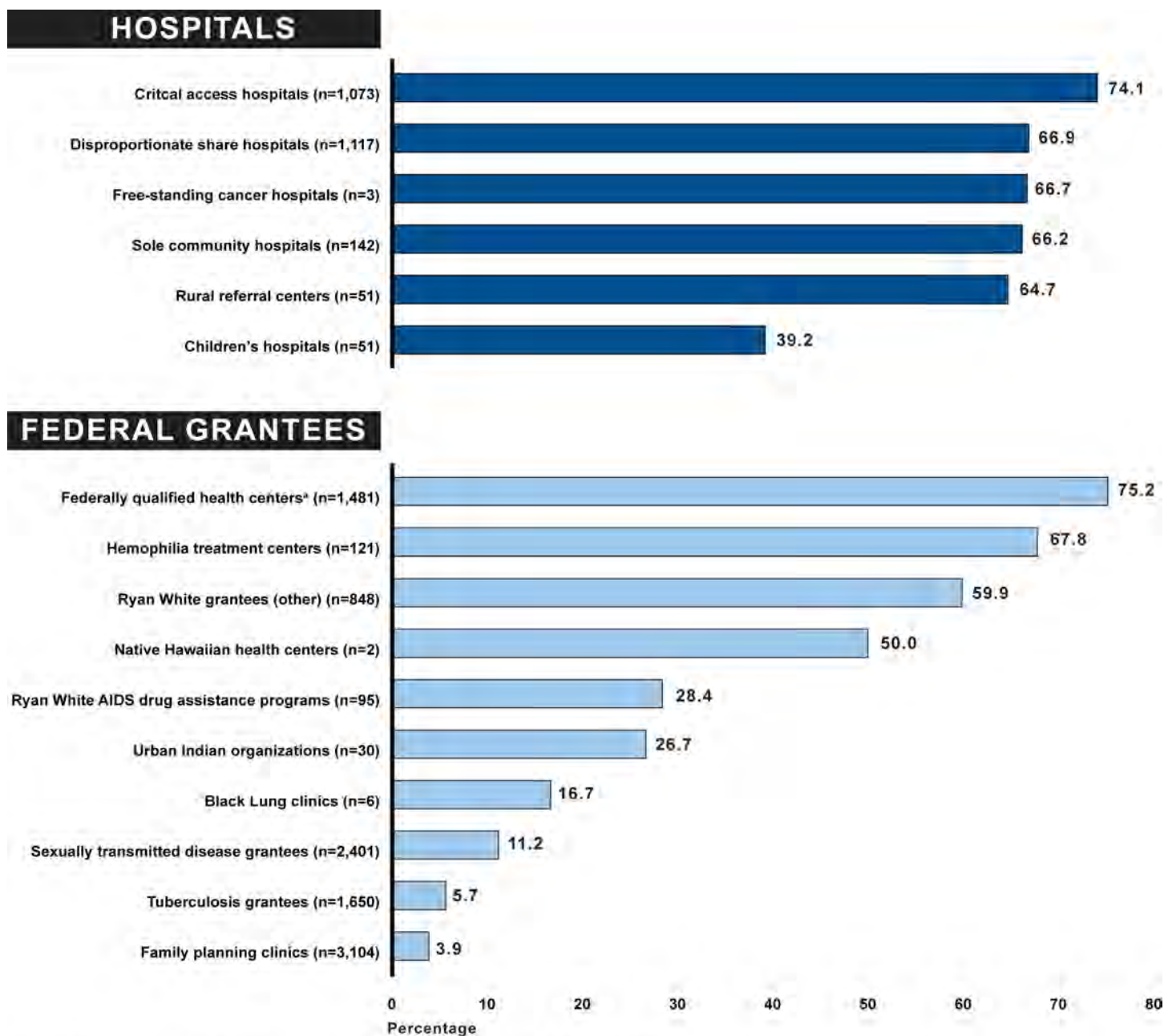
discounts.²⁹ Based on the audits for which results were posted on HRSA's website as of February 8, 2018, 72 percent of the covered entities audited in fiscal years 2012 through 2017 had one or more findings of noncompliance. When an audit of a covered entity has a finding of noncompliance, covered entities are required to submit a corrective action plan within 60 days of the audit being finalized for HRSA approval. HRSA closes out the audit once the entity attests that the corrective action plan has been fully implemented and any necessary repayments have been made to affected manufacturers.

About One-Third of Covered Entities Had One or More Contract Pharmacies, and Pharmacy Characteristics Varied

As of July 1, 2017, about one-third of the more than 12,000 covered entities in the 340B Program had contract pharmacies, but the extent to which covered entities had contract pharmacies varied by type of entity. Overall, a higher percentage of hospitals (69.3 percent) had at least one contract pharmacy compared to federal grantees (22.8 percent). Among the six types of hospitals, the percentage that had at least one contract pharmacy ranged from 39.2 percent of children's hospitals to 74.1 percent of critical access hospitals. Among the 10 types of federal grantees, the percentage with at least one contract pharmacy ranged from 3.9 percent of family planning clinics to 75.2 percent of FQHCs (see fig.4).

²⁹The audits review covered entities' policies and practices to see if the potential for duplicate discounts exists. However, in order to determine whether duplicate discounts have actually occurred, a covered entity must check with its state Medicaid agency to see if it has received rebates for the same drugs for which the entity received a discounted price.

Figure 4: Percent of Covered Entities That Had at Least One Contract Pharmacy as of July 1, 2017, by Entity Type



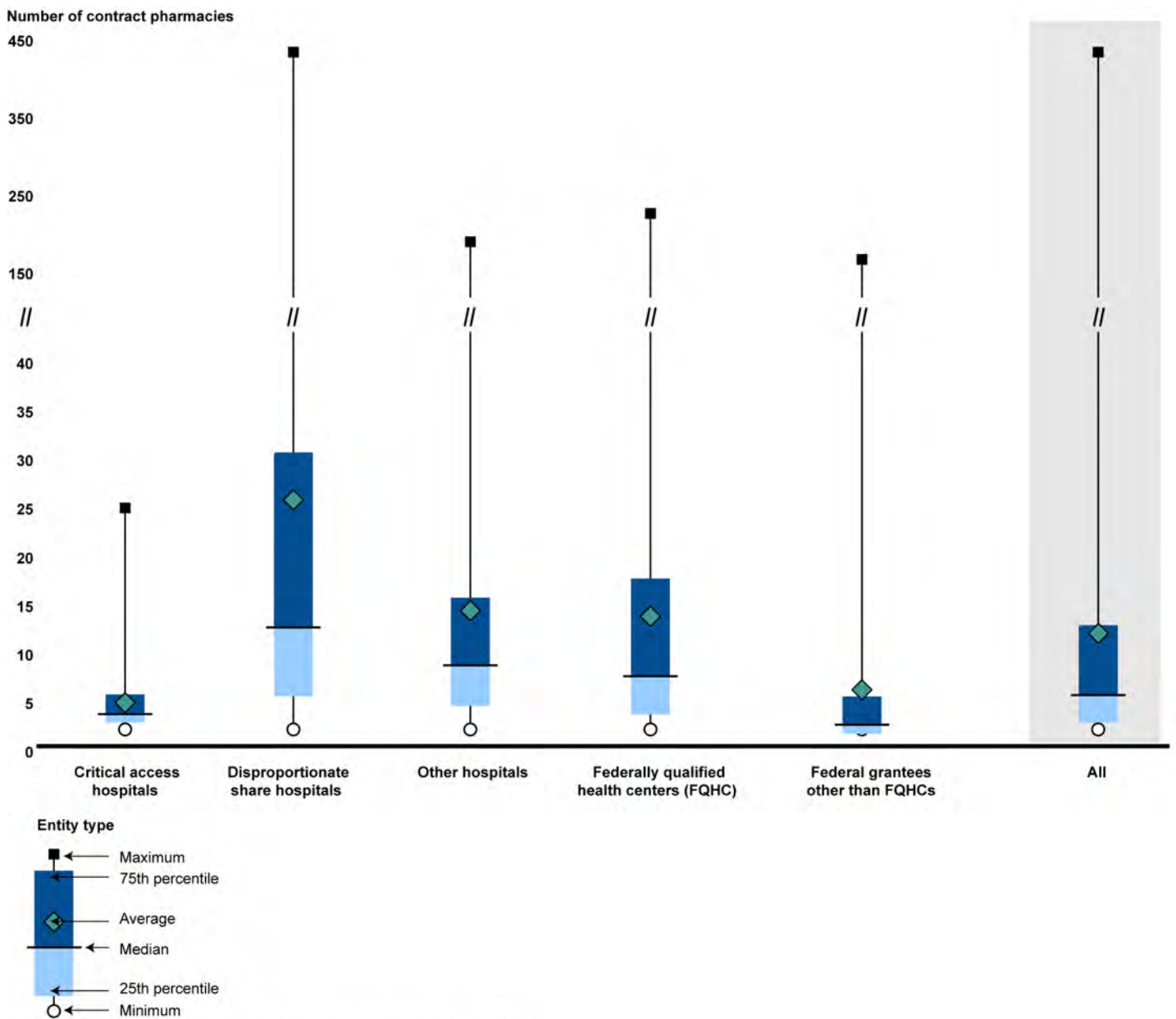
Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

*Not all federally qualified health centers (FQHCs) receive federal grants. Providers that meet all of the requirements for the FQHC program, but do not receive federal grants, are referred to as FQHC look-alikes and are eligible to participate in the 340B Program.

Among covered entities that had at least 1 contract pharmacy, the number of contract pharmacies ranged from 1 to 439, with an average of 12 contract pharmacies per entity. However, the number of contract pharmacies varied by covered entity type, with disproportionate share hospitals having the most on average (25 contract pharmacies), and critical access hospitals having the least (4 contract pharmacies).³⁰ (See fig. 5 for the distribution of contract pharmacies by covered entity type.) However, we found that a covered entity that contracts with a pharmacy may not actually use the pharmacy to dispense 340B drugs. For example, three covered entities that received our questionnaire told us that although they had one or more contract pharmacies registered with HRSA, they did not use those pharmacies to dispense 340B drugs. Moreover, officials from a covered entity we interviewed reported that while the entity maintained a contract with a specialty pharmacy, it had not dispensed 340B drugs through that pharmacy in several years. Officials explained that the covered entity maintained its contract and continued to register this pharmacy with HRSA because it would be financially beneficial should it have a patient fill a 340B-eligible specialty drug at this pharmacy in the future.

³⁰Covered entities that are hospitals or FQHCs may register multiple sites as part of the entity. Across these types of covered entities, the average number of contract pharmacies per entity site ranged from a minimum of about two per critical access hospital site to a maximum of about four per disproportionate share hospital site.

Figure 5: Distribution of Contract Pharmacies as of July 1, 2017, by Covered Entity Type



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

The actual number of 340B contract pharmacy arrangements—the number of contractual arrangements between contract pharmacies and the sites of a covered entity—is unknown because HRSA does not

require a covered entity to register pharmacies with each of its child sites. Rather, HRSA gives covered entities the option to register contract pharmacies only in relation to the parent site: child sites may use that pharmacy if included in the written contract between the entity and the pharmacy.³¹ Based on our analysis of HRSA data, 1,645 covered entities that had at least one child site registered their contract pharmacies only with their parent sites. These 1,645 covered entities had a total of 25,481 registered contract pharmacy arrangements.³² However, if the pharmacies were contracted to work with all of the covered entities' sites—the parents and all the child sites—then these 1,645 entities could have as many as 866,388 contract pharmacy arrangements.³³ Therefore, the number of contract pharmacy arrangements is likely higher than what is reported in HRSA's database.

Nearly 93 percent of the approximately 20,000 pharmacies that 340B covered entities contracted with as of July 1, 2017, were classified as community/retail pharmacies, less than 1 percent were classified as specialty pharmacies, and about 7 percent were other types of pharmacies including institutional and mail order pharmacies.³⁴ Furthermore, the majority (75 percent) of 340B contract pharmacies were chain pharmacies, while 20 percent were independent pharmacies and 5

³¹As previously noted, HRSA does not require covered entities to submit copies of all of their pharmacy contracts.

³²Since the same pharmacy may have a contract to work with multiple covered entities, the number of contract pharmacy arrangements is more than the number of pharmacies that serve as 340B contract pharmacies.

³³To determine the total possible number of arrangements, for each of the 1,645 covered entities that had multiple sites and registered their contract pharmacies only with their parent sites, we multiplied the number of sites by the number of contract pharmacies each covered entity registered with HRSA. We then summed the numbers for the 1,645 covered entities. For example, a covered entity that had five sites and 10 contract pharmacies registered only with the parent site (for a total of 10 registered contract pharmacy arrangements) could actually have a total of 50 possible arrangements.

³⁴Community/retail pharmacies are defined by DataQ as those where pharmacists prepare and dispense drugs for a local patient population, counsel patients, administer vaccinations, and provide other professional services associated with pharmaceutical care such as health screenings. Specialty pharmacies are defined as pharmacies that dispense low-volume and high-cost drugs to patients undergoing intensive therapies for illnesses that are generally chronic, complex and potentially life threatening. Some of the pharmacies categorized as community/retail pharmacies may also dispense such high-cost drugs. Other pharmacies also include those where the type is unknown. About one-tenth of one percent of all contract pharmacies (26 pharmacies) were mail order pharmacies.

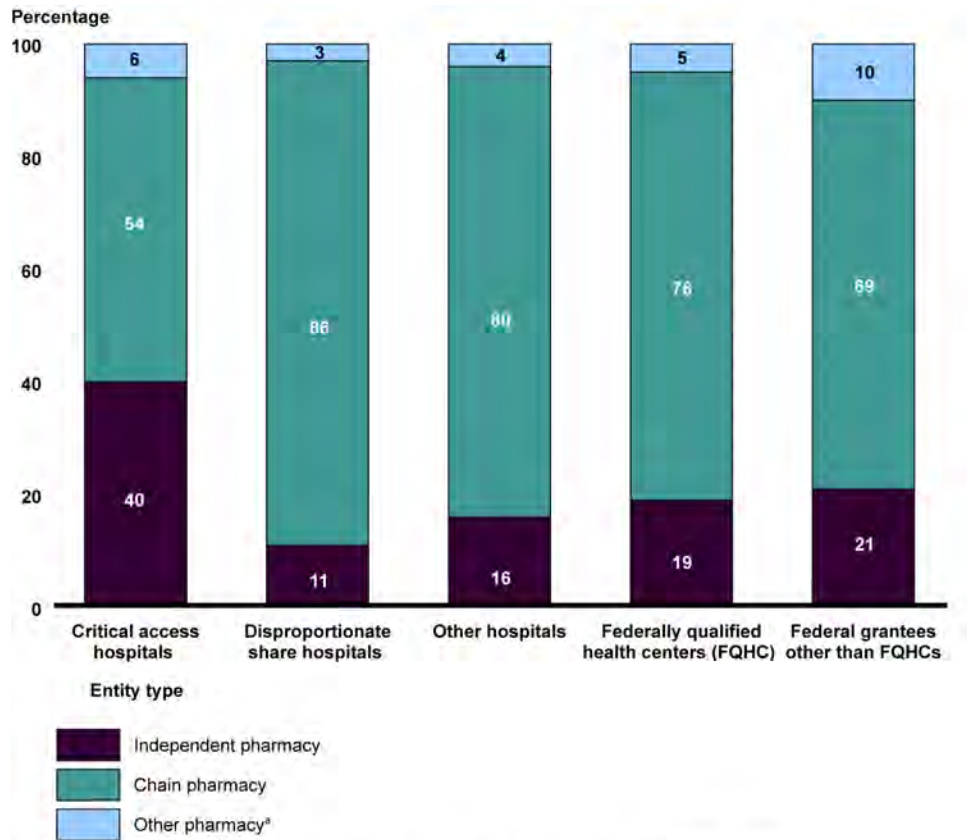
percent were other pharmacies.³⁵ In contrast, slightly over half of all pharmacies nationwide are chain pharmacies and about one-third are independent. The five biggest pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—represented a combined 60 percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide.³⁶ Figure 6 shows how the types of pharmacies varied by type of covered entity. Critical access hospitals had a higher proportion of independent contract pharmacies (40 percent of their pharmacies) compared to other covered entity types (which ranged from 11 percent for disproportionate share hospitals to 21 percent for other federal grantees). Our analysis suggests that this is likely due, in part, to a larger proportion of critical access hospitals compared to other types of covered entities being located in rural areas; independent contract pharmacies are also more likely than other contract pharmacies to be located in rural areas.³⁷

³⁵Chain pharmacies are defined by DataQ as those in which four or more pharmacies are under common ownership, while independent pharmacies have three or less locations under the same ownership or are independent pharmacies that have signed a franchisor agreement. Other pharmacies include government pharmacies, alternative dispensing sites such as physician's offices, and pharmacies for which the type of pharmacy was unknown.

³⁶Walgreens alone accounted for 31 percent of 340B contract pharmacies. Walgreens pharmacies account for only about 10 percent of all pharmacies nationwide.

³⁷We used the addresses from the 340B database, along with the Rural Urban Commuting Area—a system for geographic classification, to determine whether covered entities and pharmacies were located in rural or urban areas.

Figure 6: Percent of 340B Program Contract Pharmacies by Pharmacy and Covered Entity Type, as of July 1, 2017



Source: GAO analysis of Health Resources and Services Administration data and DataQ data. | GAO-18-480

Note: We used the National Council for Prescription Drug Programs' DataQ to identify pharmacy type. DataQ is a database from the National Council for Prescription Drug Programs, which contains information reported by pharmacies that is used by health care payers and claims processors across the country to identify pharmacies.

^a"Other pharmacy" includes government pharmacies, alternative dispensing sites—such as physician offices, and pharmacies for which the type of pharmacy was unknown.

Across all covered entities, the distance between the entities and their contract pharmacies ranged from 0 miles (meaning that the contract pharmacy and entity were co-located) to more than 5,000 miles; the

median distance was 4.2 miles.³⁸ Table 3 shows the distribution of distances between covered entities and their pharmacies overall and by entity type.

Table 3: Distance (in Miles) between Covered Entities and Their Contract Pharmacies as of July 1, 2017, by Entity Type

Entity type	Minimum	25th percentile	Median	75th percentile	Maximum
Disproportionate share hospitals	0	1.5	4.7	25.4	5,052
Critical access hospitals	0	0.6	3.6	28.7	2,495
Other hospitals	0	1.5	5.9	35.7	3,422
Federally qualified health centers (FQHC)	0	0.8	2.4	7.0	4,666
Federal grantees other than FQHCs	0	4.6	19.9	123.7	2,711
All entities	0	1.2	4.2	20.7	5,052

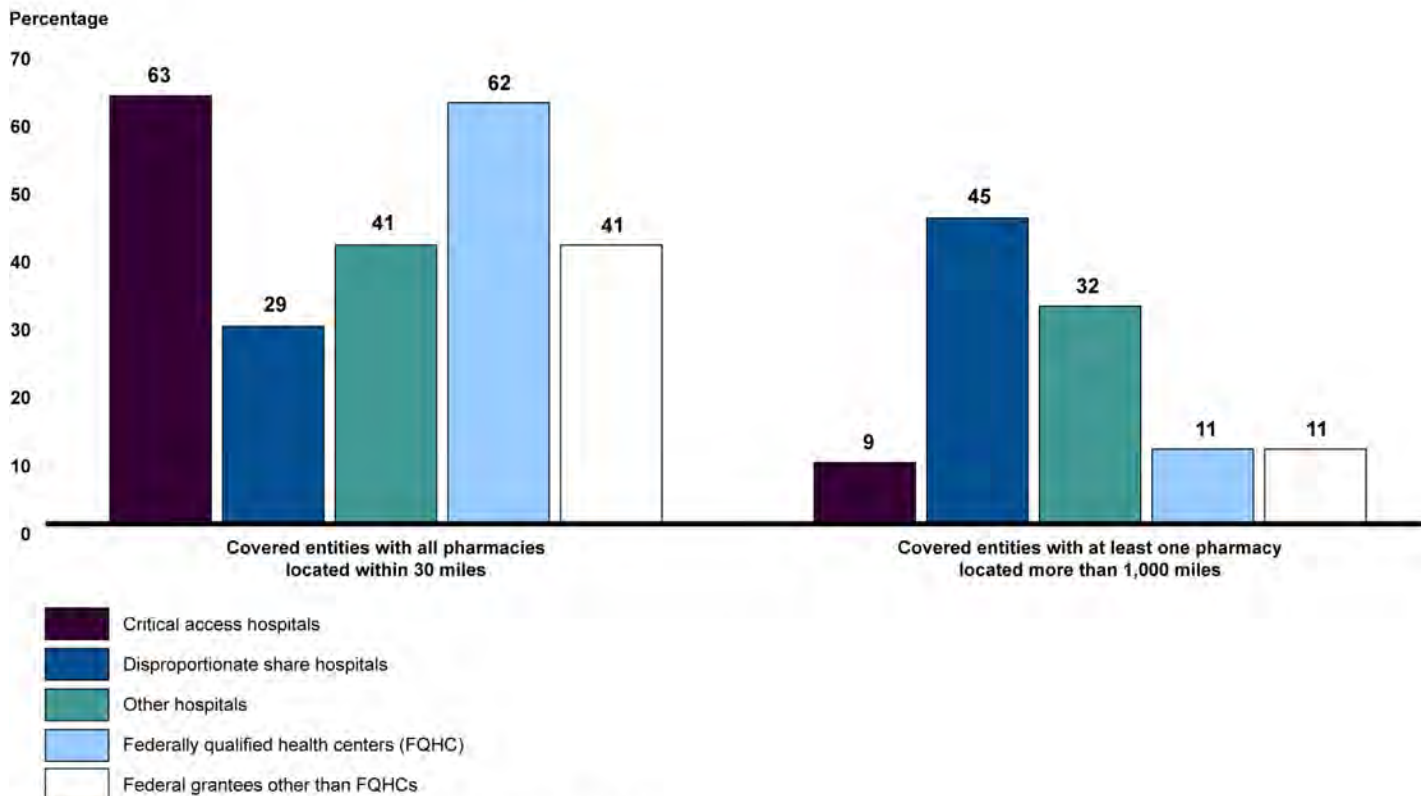
Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

Note: Distance was measured from the contract pharmacy to the closest site of the entity. Mail order pharmacies were excluded from distance calculations.

While there was a range in distances between covered entities and each of their pharmacies, about half of the entities had all their contract pharmacies located within 30 miles, but this varied by entity type. Specifically, more than 60 percent of critical access hospitals and FQHCs had all of their contract pharmacies within 30 miles. In contrast, 45 percent of disproportionate share hospitals had at least one pharmacy that was more than 1,000 miles away compared to 11 percent or less for grantees and critical access hospitals. (See fig. 7.)

³⁸Distance between a covered entity and its contract pharmacies was measured from the pharmacy to the closest site of the entity. We excluded mail order pharmacies from distance calculations. The maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut that contracted with a pharmacy in Hawaii. The 340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away. When asked why contract pharmacies may be located many miles away from the covered entity, HRSA officials indicated that the pharmacies may provide prescriptions by mail (even if they are not classified as mail order pharmacies) or dispense specialty drugs. In addition, HRSA officials noted that some covered entities may serve patients who live far away from the entity and thus have contracts with pharmacies located close to where their patients reside.

Figure 7: Percent of Covered Entities with Contract Pharmacies within Given Distances as of July 1, 2017, by Entity Type



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

Note: Distance was measured from the contract pharmacy to the closest site of the covered entity. Mail order pharmacies were excluded from distance calculations.

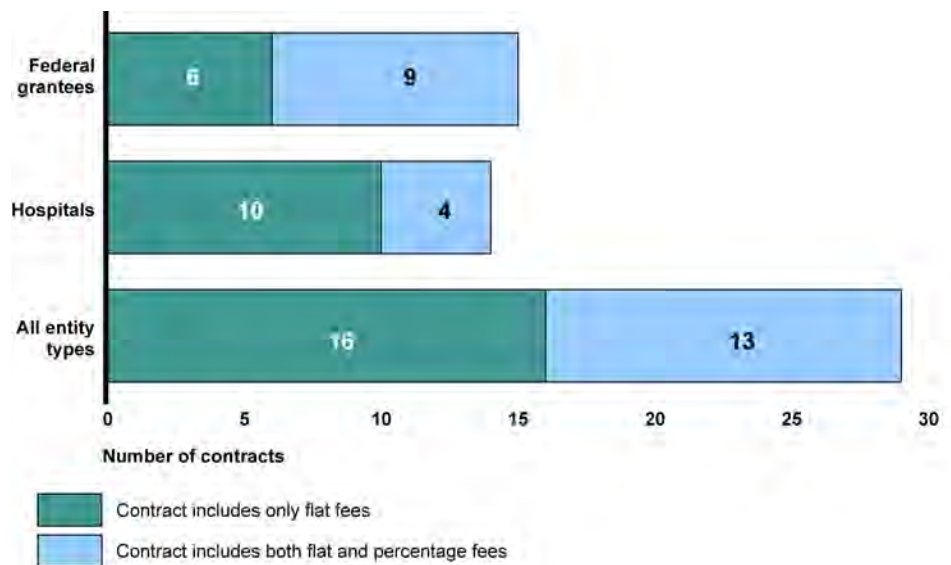
Selected Covered Entities Used Various Methods to Pay Contract Pharmacies and TPAs

Contracts we reviewed between selected covered entities and contract pharmacies showed that entities generally agreed to pay their contract pharmacies a flat fee per 340B prescription, with some entities also paying additional fees based on a percentage of revenue. Selected covered entities and TPAs included in our review indicated two main methods entities use to pay for TPA services: 1) per prescription processed, or 2) per contract pharmacy.

Contracts Reviewed Showed Covered Entities Agreed to Pay Contract Pharmacies a Fee per 340B Prescription; Some Also Agreed to Additional Fees

Twenty-nine of the 30 contracts we reviewed between covered entities and contract pharmacies included provisions for the entities to pay flat fees for each eligible 340B prescription. For the remaining contract, the covered entity and the contract pharmacy were part of the same hospital system, and the contract provided that the entity would not pay fees for 340B prescriptions. In addition to payment of flat fees, 13 of the 29 contracts required the covered entity to pay the contract pharmacy a fee based on a percentage of revenue generated for each 340B prescription. Among the contracts we reviewed, more federal grantees than hospitals had contracts that included both flat fees and fees based on the percentage of revenue (see fig. 8).

Figure 8: Types of Fees Included in Selected Contracts between Covered Entities and Pharmacies, by Entity Type



Source: GAO review of selected 340B contracts. | GAO-18-480

Note: We reviewed a total of 30 contracts between covered entities and pharmacies that HRSA collected during audits of entities between fiscal years 2014 and 2016. One contract was between a covered entity and a pharmacy that were part of the same hospital system, which did not require the entity to pay fees for 340B prescriptions. As a result, the total number of contracts we reviewed with fees was 29.

Example of Fees between a Covered Entity and Contract Pharmacy

In the hypothetical example below, the contract pharmacy receives a total reimbursement of \$100 for providing an eligible patient with a 340B drug. Pursuant to a contract with the covered entity, the contract pharmacy deducts its fee of \$15, and forwards the remaining balance of \$85 to the third-party administrator (TPA).



Source: GAO. | GAO-18-480

We found a wide range in the amount of flat fees covered entities agreed to pay pharmacies in the contracts we reviewed, though they generally ranged from \$6 to \$15 per 340B prescription.³⁹ (See Appendix I for a description of fees listed in each of the contracts we reviewed.) The amount of the flat fees per 340B prescription varied by several factors according to our review, including covered entity type, type of drug, and patient insurance status:

- **Flat fees were generally higher for hospitals than federal grantees.** In general, hospitals' flat fees were higher than those for grantees, with most flat fees ranging from \$15 to \$25 per 340B prescription for hospitals, compared to from \$6 to \$13 for grantees.
- **Flat fees were sometimes higher for brand drugs.** Three of the 29 contracts we reviewed specified different flat fees for brand and generic drugs. In 2 of these contracts flat fees were \$5 or \$7 higher for brand drugs. In the remaining contract, the fees for some brand drugs were substantially higher, ranging from \$75 to \$1,750 for brand drugs, compared to \$0 for generic drugs. Additionally, some contracts we reviewed only specified a fee for brand drugs, and 4 of the contracts either excluded generic drugs from being purchased at the 340B price or limited the use of the 340B Program to brand drugs.
- **Flat fees were different or substantially higher for certain specialty drugs.** For 2 of the 29 contracts we reviewed, flat fees were for drugs to treat hemophilia.⁴⁰ Given the different nature of hemophilia treatment drugs, fees for these drugs were different than those in the other contracts for other types of drugs, and provided for payments of \$.06 and \$.09 per unit of blood clotting factor. Additionally, 2 contracts contained substantially higher flat fees for specialty medications. In 1 contract, the flat fees were \$125 per prescription for brand and generic human immunodeficiency virus drugs, and \$1,750 for brand hepatitis C drugs. In another contract the flat fees were \$65 for all specialty drugs, compared to \$13 for other drugs.

³⁹Overall, the flat fees ranged from \$0 to \$1,750 per eligible 340B prescription. Both ends of this range came from the same contract, which provided for a flat fee of \$0 for some generic drugs, but included higher fees for other drugs, including a fee of \$1,750 for brand drugs used to treat hepatitis C.

⁴⁰Hemophilia is a bleeding disorder in which the blood does not clot normally. The main treatment for the disease is to provide patients with infusions of blood clotting factor containing a protein to aid in clotting.

-
- **Flat fees were sometimes higher for 340B prescriptions dispensed to patients with insurance.** Seven of the 29 contracts we reviewed specified different flat fees for prescriptions provided to patients with health insurance than for patients paying with cash or through a drug discount card provided by the covered entity.⁴¹ The flat fees entities would pay under these contracts ranged from \$1 to \$16 higher per 340B prescription dispensed to insured patients compared to patients not using insurance.

As previously noted, in addition to requiring flat fees for dispensing prescriptions, 13 of the 29 contracts we reviewed included provisions for the covered entity to pay the pharmacy a fee based on the percentage of revenue generated by each prescription. These percentage fees only applied to prescriptions provided to patients with insurance, and ranged from 12 to 20 percent of the revenue generated by the prescriptions. Generally there were two methods for determining the amount of revenue generated. The first method used the reimbursement the pharmacy received for the prescription, while the second method used the net revenue after subtracting the 340B cost of the drug from the reimbursement received by the pharmacy.⁴²

Selected Covered Entities Use Two Main Methods to Pay TPAs

Officials from the two TPAs we interviewed and questionnaire respondents from the 39 covered entities that use TPAs described two main methods entities use to reimburse TPAs for 340B services: 1) a fee for each prescription processed by the TPA, and 2) a fee for each contract pharmacy for which the TPA processes 340B claims on behalf of the entity.

⁴¹Six of these contracts between grantees and a contract pharmacy had provisions for patients to use a drug discount card provided by the grantee to pay for prescriptions. When presented at the pharmacy, the pharmacy uses the discount card to verify the patient is 340B eligible and determine the amount the patient pays for the prescription.

⁴²Some contracts included applicable patient copayments as part of the reimbursement, while others just used the reimbursement received from the patient's health insurance.

Example of Fees between a Covered Entity and Third-Party Administrator (TPA)

In the hypothetical example below, the TPA receives \$85 from the contract pharmacy. This amount represents the total reimbursement for the 340B drug, less fees deducted by the contract pharmacy. Pursuant to an agreement with the covered entity, the TPA deducts a fee of \$5, and forwards the remaining balance of \$80 to the covered entity. This represents the total revenue the covered entity generated from the 340B drug.



Source: GAO. | GAO-18-480

Officials with the two TPAs we interviewed told us that their agreements with covered entities most frequently involve covered entities compensating them based on a fee for each prescription they process on behalf of the entity. Officials from one of these TPAs described three different fee-per-prescription options they offer to covered entities, with the amount of the fees varying based on the option selected:

- A small fee, for example, 20 cents, for every prescription filled by the covered entity's contract pharmacy, and reviewed and processed by the TPA. This includes prescriptions that may not have originated from the covered entity, and may not be 340B eligible, as contract pharmacies can also fill prescriptions for individuals who are not patients of the entity.
- A mid-sized fee, for example, \$1.90, for each prescription filled by the covered entity's contract pharmacy that the TPA reviewed and determined originated from the covered entity. These prescriptions may or may not be 340B eligible.
- A larger fee, for example, \$5 to \$7, for each prescription filled by the covered entity's contract pharmacy that the TPA determined originated from the entity and is 340B eligible.

The 39 covered entities that responded to our questionnaire and reported using a TPA most frequently reported paying their TPAs a fee per each prescription processed, but the exact method varied. For example, some covered entities said they paid their TPAs for each prescription regardless of whether it was determined to be 340B eligible, others limited the fees to prescriptions that were 340B eligible, and some reported paying TPAs for 340B-eligible prescriptions dispensed to an insured patient. (See table 4.)

Table 4: Examples of Methods Used by 39 Covered Entities to Pay Third-Party Administrators (TPA) for Reviewing and Processing 340B Prescriptions

Method used to pay TPA	Number of entities reporting this method
Per prescription processed, regardless of whether the prescription was 340B-eligible	16
Per 340B-eligible prescription processed and dispensed, regardless of the patient's insurance status	15
Flat fee per contract pharmacy for which the TPA has administration responsibilities	11
Per 340B-eligible prescription processed and dispensed to an insured patient	8
Percentage of the difference between the 340B price and the reimbursement received for the drug	7
Per 340B-eligible prescription processed and dispensed to an insured patient and a percentage of the difference between the 340B price and the reimbursement received for the drug	2
Flat fee (e.g., fee per month)	3

Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, and 39 said they used TPAs to review and process 340B prescriptions. Several of the covered entities indicated that they used more than one method to pay TPAs for their services, thus the numbers in the table will not add to 39.

Among the 10 covered entities we interviewed, officials from 8 of these entities said they used TPAs; 5 said they pay their TPAs a fee per prescription, 1 reported paying a fee per contract pharmacy, and 2 reported using both options.⁴³ Among the covered entities that used fees per prescription and told us the amounts of the fees they pay, the fees ranged from \$3.50 to \$10.00 per 340B eligible prescription or \$3.95 per prescription regardless of whether the prescription was 340B eligible.⁴⁴

⁴³For the two covered entities that reported using both methods to pay their TPAs, one had two TPAs, each of which they paid using a different method, while the other said it paid the TPA differently for each of its contract pharmacies.

⁴⁴Five of the seven covered entities that reported paying their TPA a fee per prescription provided information on the amount of that fee, one of which said it paid a fee regardless of whether the prescription was 340B eligible.

For those that pay their TPA a fee per contract pharmacy, the fee was \$25,000 a year per pharmacy.⁴⁵

About Half of the Covered Entities Reviewed Provided Low-Income, Uninsured Patients Discounts on 340B Drugs at Some or All of Their Contract Pharmacies

Of the 55 covered entities responding to our questionnaire, 30 reported providing low-income, uninsured patients discounts on 340B drugs dispensed at some or all of their contract pharmacies, and 25 said they did not offer discounts at their contract pharmacies.⁴⁶ All 30 covered entities providing patients with discounts reported providing discounts on the drug price for some or all 340B drugs dispensed at contract pharmacies.⁴⁷ Federal grantees were more likely than hospitals to provide such discounts and to provide them at all contract pharmacies (see fig. 9).⁴⁸

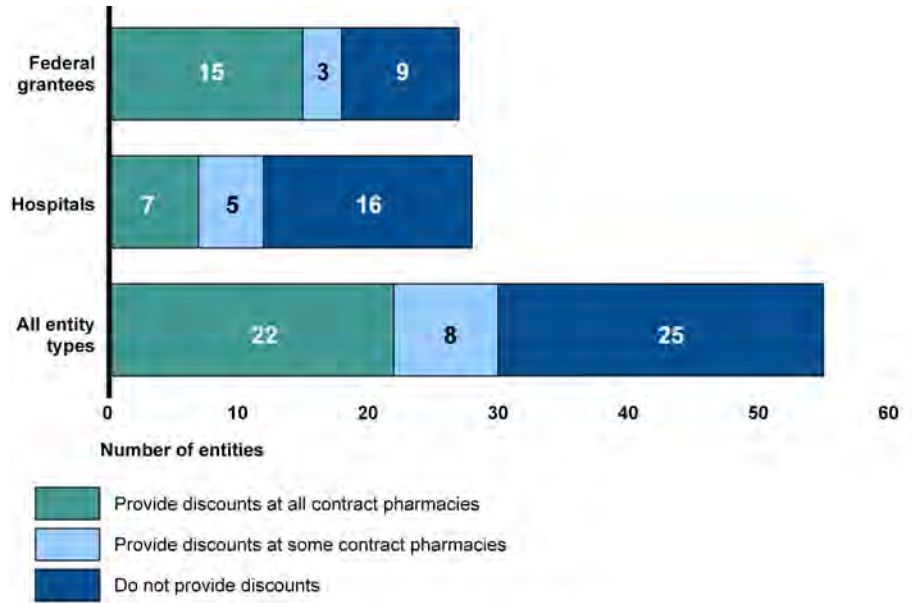
⁴⁵Two of the three covered entities that reported paying their TPA a fee per pharmacy provided information on the amount of that fee. One of those covered entities split the fee with other covered entities that were part of the same hospital system, and thus was responsible for a smaller portion of the fee.

⁴⁶In contrast, 17 of the 23 covered entities that had in-house pharmacies reported offering discounts at those pharmacies, including 4 entities that did not offer discounts at their contract pharmacies.

⁴⁷In our questionnaire, a discount on the drug price was defined as charging the patient less than the wholesale price—the price that a wholesaler charges a pharmacy for a drug—or what a self-paying patient would pay.

⁴⁸While not a requirement of the 340B Program, covered entities that became eligible for the program as a result of being federal grantees may have requirements as part of their grants related to the use of 340B revenue or the provision of discounts to patients.

Figure 9: Number of Selected Covered Entities that Reported Providing Discounts to Low-Income, Uninsured Patients on the Price of 340B Drugs Dispensed at Contract Pharmacies, by Entity Type

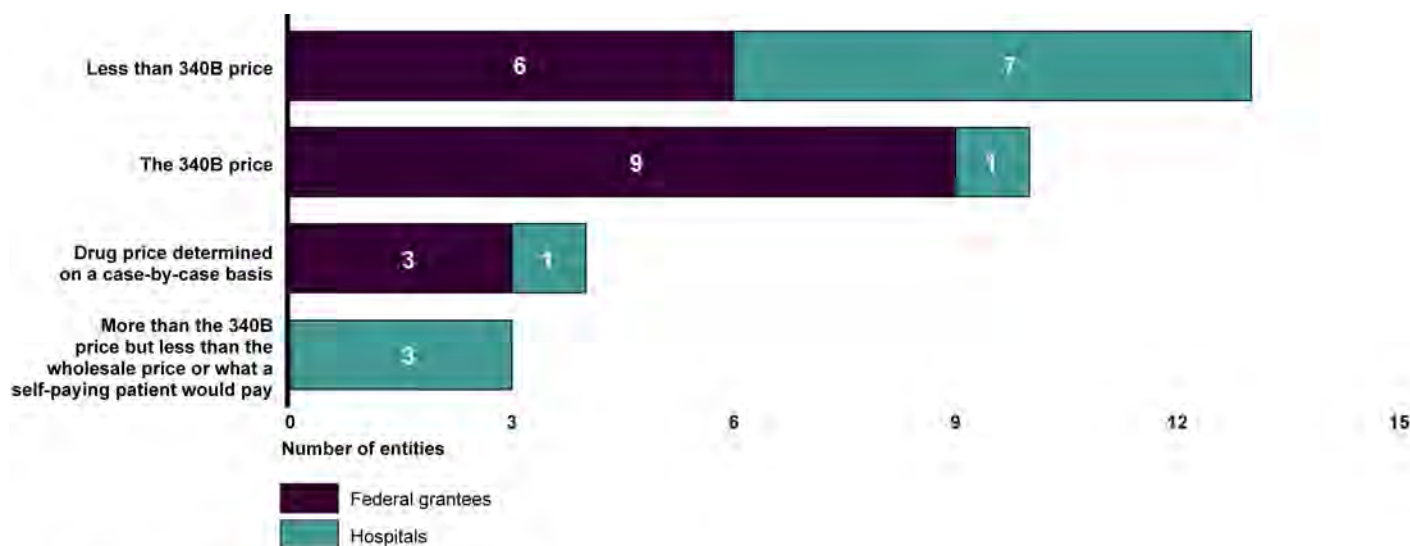


Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities; 55 entities responded.

Of the 30 covered entities that responded to our questionnaire that they provided discounts on the drug price, 23 reported providing patients the full 340B discount—the patients obtained drugs from contract pharmacies at the 340B price or less. In many cases, these covered entities indicated that patients received drugs at no cost. Some covered entities reported that patients would pay more than the 340B price, but less than the wholesale price of the drug or what a self-paying patient would pay, and others indicated they determined discounts for patients on a case-by-case basis. A larger number of federal grantees than hospitals (15 compared to 8) indicated their patients would pay the 340B price or less for their drugs at contract pharmacies where discounts were available. (See fig. 10.)

Figure 10: Prices Patients Pay for 340B Drugs for 30 Covered Entities That Reported Providing Discounts at Their Contract Pharmacies, by Entity Type



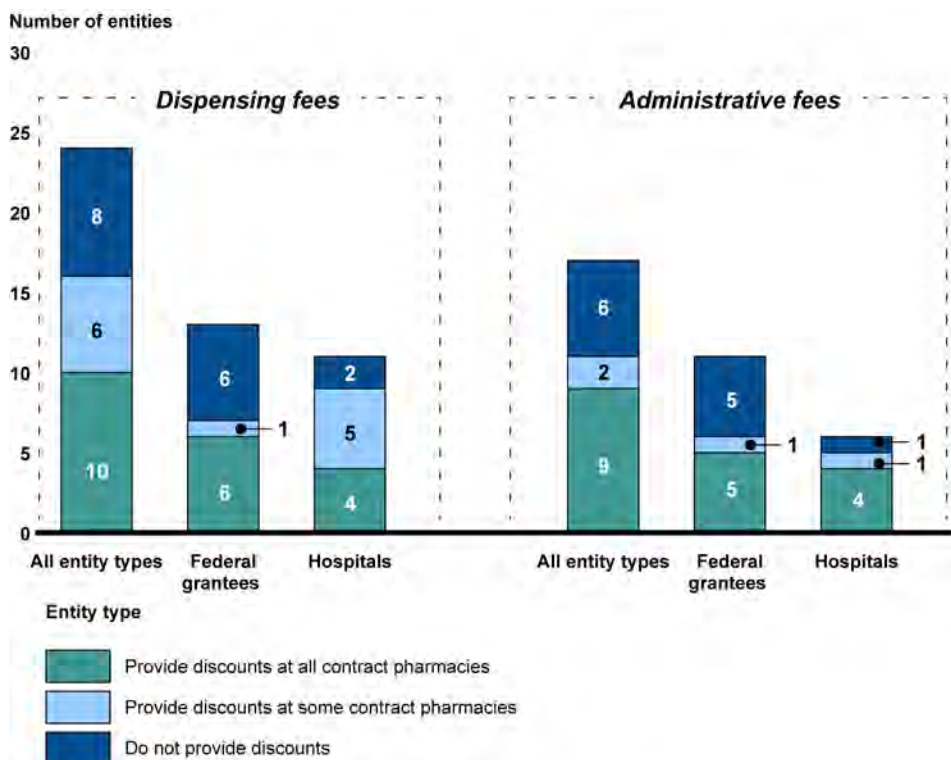
Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients.

In addition to providing discounts on the 340B drug price, some of the 30 covered entities also reported providing discounts on fees patients may pay to contract pharmacies for 340B drugs. Contract pharmacies may charge fees to dispense 340B drugs or cover administrative costs of participating in a covered entity's 340B program, including costs associated with tracking drug inventories and ordering new drugs.⁴⁹ In general, about two-thirds of the covered entities with patients who would be subject to dispensing or administrative fees at contract pharmacies reported providing discounts on the fees at some or all of their contract pharmacies. Hospitals were more likely than grantees to provide discounts on these fees when applicable. (See fig.11.)

⁴⁹Six of the 30 covered entities indicated they did not charge patients dispensing fees through their contract pharmacies, and 13 did not charge administrative fees. Therefore, discounts on dispensing fees could be applicable to 24 covered entities (13 federal grantees and 11 hospitals), and discounts on administrative fees could be applicable to 17 covered entities (11 federal grantees and 6 hospitals).

Figure 11: Number of Selected Covered Entities That Reported Providing Discounts on Dispensing and Administrative Fees at Contract Pharmacies, by Entity Type



Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities, and 55 provided responses. Data shown are for the 30 covered entities that reported providing discounts to low-income, uninsured patients at contract pharmacies. Six of the 30 covered entities indicated they did not charge patients dispensing fees through their contract pharmacies, and 13 did not charge administrative fees. Therefore, discounts on dispensing fees could be applicable to 24 covered entities, and discounts on administrative fees could be applicable to 17 covered entities.

The 30 covered entities providing 340B discounts to low-income, uninsured patients reported using a variety of methods to determine whether patients were eligible for these discounts. Fourteen of the covered entities said they determined eligibility for discounts based on whether a patient's income was below certain thresholds as a percentage of the federal poverty level, 11 reported providing discounts to all patients, and 5 said they determined eligibility for discounts on a case-by-case basis. For those 14 covered entities determining eligibility based on income as a percentage of the federal poverty level, the threshold used to determine who was eligible for discounts varied but most reported that

patients with incomes at or below 250 percent of the federal poverty level would be eligible for discounts. (See table 5.)

Table 5: Income Thresholds Used by Selected Covered Entities to Determine Eligibility for 340B Discounts, by Entity Type

Income threshold as a percent of the federal poverty level	Number of federal grantees	Number of hospitals	Total number of entities
100	2	0	2
200	4	1	5
225	0	1	1
250	0	2	2
300	1	1	2
350	0	1	1
500	1	0	1
Total	8	6	14

Source: Responses to GAO's questionnaire to 340B covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients. Of those 30 covered entities, 14 reported determining eligibility for discounts based on a patient's income as a percentage of the federal poverty level. In 2018, the federal poverty level in the continental United States was \$25,100 a year for a family of four.

Covered entities reported making patients aware of the availability of discounts at contract pharmacies primarily through oral communication by staff located at either the entity or the pharmacy. In addition, the covered entities reported using a variety of methods to inform contract pharmacies about which patients were eligible for discounts, including through notes in patient medical records sent to the pharmacy or by placing codes on the patient's prescriptions sent to or presented at the pharmacy. (See table 6.) Officials from one covered entity we interviewed said that it provides patients eligible for discounts with an identification card (which they referred to as a drug discount card) that patients present at the contract pharmacy; this card informs pharmacy staff of the specific discount amount. Officials from another covered entity said they place codes on electronic prescriptions which informs the pharmacy about discounts.

Table 6: Examples of Methods Used by 30 Covered Entities to Inform Contract Pharmacies of Patients' Eligibility for Discounts

Method used by covered entity	Number of covered entities
Providing patient eligibility files or electronic medical records to pharmacy	11
Placing codes or annotations on electronic prescriptions with discount information	10
Relying on pharmacist familiarity with patients, providers and medications	8
Placing stamps or notations on paper prescription	6
Using identification cards with patient information	6
Providing patients with copayment assistance cards or debit cards to present at pharmacy	3

Source: Responses to GAO's questionnaire to 340B covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients. Twelve of the 30 covered entities reported using two or more methods to inform pharmacies about patients' eligibility for discounts, thus the numbers in the table do not add to 30.

Some covered entities that did not provide discounts on 340B drugs at their contract pharmacies reported assisting patients with drug costs through other mechanisms. For example, 6 of the 10 covered entities we interviewed said that while they did not provide discounts on 340B drugs dispensed at their contract pharmacies, they provide charity care to low-income patients, including free or discounted prescriptions. Additionally, 4 of the 25 covered entities that reported on our questionnaire that they did not provide discounts at their contract pharmacies said they provided patients with discounts on 340B drugs at their in-house pharmacies.

Oversight Weaknesses Impede HRSA's Ability to Ensure Compliance at 340B Contract Pharmacies

HRSA does not have complete data on the total number of contract pharmacy arrangements in the 340B Program to inform its oversight efforts, including information that could be used to better target its audits. Additionally, weaknesses in HRSA's audit process compromise its oversight of covered entities. Finally, the lack of specificity in HRSA's guidance to covered entities potentially impedes covered entities' oversight of contract pharmacies.

HRSA Does Not Have Complete Data on Contract Pharmacy Arrangements to Use for Its Oversight

HRSA does not have complete data on all contract pharmacy arrangements in the 340B Program to inform its oversight efforts. HRSA requires covered entities to register their contract pharmacies with the agency and recertify that registration annually. Contract pharmacies registered to each covered entity are recorded in a publicly available database, which according to HRSA, is used by various stakeholders to validate the eligibility of entities and confirm shipping addresses for each contract pharmacy eligible to receive 340B drugs on an entity's behalf. However, because covered entities differ in the way they register their contract pharmacies, HRSA, and its publicly available database, does not have information on all of an entity's contract pharmacy arrangements. Specifically, because HRSA does not require covered entities to separately register contract pharmacies to each child site for which a contractual relationship exists, HRSA does not have complete information on which sites of an entity have contracted with a pharmacy to dispense 340B drugs. Our analysis of HRSA data showed that the registration of contract pharmacies for 57 percent of covered entities with child sites only specified relationships between contract pharmacies and the parent site; thus HRSA may only have information on a portion of the actual number of 340B contract pharmacy arrangements. Additionally, manufacturers do not have complete information on which covered entity sites have contracts with a pharmacy to dispense 340B drugs, according to HRSA officials. Manufacturers could use such information to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site.

HRSA officials told us that the number of contract pharmacy arrangements recorded in HRSA's database increases a covered entity's chance of being randomly selected for a risk-based audit. However, since HRSA gives covered entities multiple contract pharmacy registration options, the likelihood of an entity being selected for an audit is dependent, at least in part, on how an entity registers its pharmacies as opposed to the entity's actual number of pharmacy arrangements. Without more complete information on covered entities' contract pharmacy arrangements, HRSA cannot ensure that it is optimally targeting the limited number of risk-based audits done each year to entities with more contract pharmacy arrangements. Federal internal control standards related to information and communication state that management should use quality information to achieve the entity's objectives, such as by obtaining relevant data that are reasonably free from error and bias and represent what they purport to represent so that

they can be used for effective monitoring.⁵⁰ Without complete information on covered entities' use of contract pharmacies, HRSA does not have the information needed to effectively oversee the 340B Program, including information that could be used to better target its audits of covered entities.

Weaknesses in HRSA's Audit Process Impede Its Oversight of 340B Program Compliance at Contract Pharmacies

HRSA primarily relies on audits to assess covered entities' compliance with 340B Program requirements, including compliance at contract pharmacies, according to HRSA officials; however weaknesses in its audit process impede the effectiveness of its oversight.⁵¹ As a result of its audits, HRSA has identified instances of diversion and the potential for duplicate discounts at contract pharmacies, among other findings of noncompliance. Specifically, through the audits conducted since fiscal year 2012, HRSA identified at least 249 instances of diversion at contract pharmacies and 15 instances of the potential for duplicate discounts for drugs dispensed at contract pharmacies, as of February 2018. HRSA had also identified 33 covered entities with insufficient contract pharmacy oversight. (See Table 7.)

⁵⁰[GAO-14-704G](#).

⁵¹In addition to audits, other mechanisms HRSA uses to oversee compliance at contract pharmacies include the agency's registration and annual recertification process; its collection of contracts for 5 percent of newly registered contract pharmacies; and its self-disclosure process, whereby covered entities can report any material compliance breaches, and steps to address the breach, to HRSA.

Table 7: Summary of Health Resources and Services Administration’s (HRSA) Audit Findings Related to Contract Pharmacies, as of February 8, 2018

Fiscal Year	Diversion Findings			Duplicate Discount Findings			Contract pharmacy oversight findings
	Total	Number at contract pharmacies	Percent at contract pharmacies	Total	Number at contract pharmacies	Percent at contract pharmacies	
2012	16	9	56	18	3	17	0
2013	52	22	42	25	1	4	5
2014	54	38	70	23	1	4	9
2015	95	65	68	46	3	7	9
2016	94	64	68	55	6	11	7
2017 ^a	69	51	74	39	1	3	3
Total	380	249	66	206	15	7	33

Source: GAO analysis of HRSA data. | GAO-18-480

Notes: A diversion finding indicates that a covered entity dispensed 340B drugs to an individual who did not meet HRSA’s definition of a patient. A duplicate discount finding indicates the potential that drugs prescribed to Medicaid beneficiaries were subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. A contract pharmacy oversight finding indicates that a covered entity did not perform any type of oversight activities for its contract pharmacies.

^aData for fiscal year 2017 are not complete because not all audits had been closed at the time of our review—as of February 8, 2018. Therefore, the number of findings for that fiscal year could increase depending on the results of the remaining audits.

However, we identified two areas of weaknesses in HRSA’s audit process that impede its oversight of covered entities’ compliance with 340B Program requirements at contract pharmacies: 1) the process does not include an assessment of all potential duplicate discounts, and 2) the process for closing audits does not ensure all covered entities have fully addressed any noncompliance identified.

Medicaid Delivery Systems

States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, states reimburse providers directly for each service delivered. For example, a pharmacy would be paid by the state for each drug dispensed to a Medicaid beneficiary. Under a capitated managed care model, states typically contract with managed care organizations to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pays each organization a set amount per beneficiary per month to provide or arrange those services.

Source: GAO. | GAO-18-480

Not all potential duplicate discounts are assessed. HRSA's audits only assess the potential for duplicate discounts in Medicaid fee-for-service. They do not include a review of covered entities' processes to prevent duplicate discounts for drugs dispensed through Medicaid managed care.⁵² The potential for duplicate discounts related to Medicaid managed care has existed since 2010 when manufacturers were required to pay Medicaid rebates under managed care, and currently, there are more Medicaid enrollees, prescriptions, and spending for drugs under managed care than fee-for-service.⁵³

HRSA officials told us that they do not assess the potential for duplicate discounts in Medicaid managed care as part of their audits because they have yet to issue guidance as to how covered entities should prevent duplicate discounts in Medicaid managed care.⁵⁴ They agreed that the lack of Medicaid managed care guidance for covered entities was problematic, and HRSA's December 2014 policy release stated, "HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with the Centers for Medicare & Medicaid Services (CMS) to develop policy in this regard."⁵⁵ According to HRSA, in the absence of formal guidance, covered entities should work with their states to develop strategies to prevent duplicate discounts in Medicaid managed care. However, 8 of the 10 covered entities we spoke with described challenges working with their

⁵²While HRSA does not include an assessment for duplicate discounts related to Medicaid managed care claims as part of its audit process, beginning April 1, 2018, if the agency becomes aware of the potential for such duplicate discounts during the course of an audit, then it will note this in the audit report for the covered entity. If the audit of the covered entity results in findings, then the entity would be required to indicate how it will address the duplicate discounts.

⁵³According to analysis from the Medicaid and CHIP Payment and Access Commission, in fiscal year 2016, almost 60 percent of Medicaid gross spending for drugs and almost 70 percent of Medicaid drug prescriptions were in managed care. Additionally, as of July 2015, about 65 percent of Medicaid enrollees received their medical care services through managed care.

⁵⁴Federal law directs HRSA to provide guidance to covered entities regarding the prevention of duplicate discounts. 42 U.S.C. § 256b(d)(2)(B)(iii). In 1993, HRSA issued final guidance for the prevention of duplicate discounts in Medicaid fee-for-service, establishing that HHS will provide covered entity Medicaid provider numbers to the state Medicaid agencies on a regular basis. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (Jun. 23, 1993). This information is referred to as the Medicaid Exclusion File.

⁵⁵See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014). CMS is the HHS agency responsible for overseeing state Medicaid programs.

states and local Medicaid managed care organizations to ensure that duplicate discounts were not occurring or expressed the need for more guidance from HRSA on how to comply with 340B requirements related to duplicate discount prevention. As a result of these challenges, some covered entities acknowledged that they did not have assurance that duplicate discounts were not occurring with their Medicaid managed care claims, while other entities told us that they did not seek discounts for the drugs of managed care patients due to compliance challenges.

Federal internal control standards related to control activities and monitoring state that agencies should 1) implement control activities through policies, such as by determining the necessary policies based on the objectives and related risks for the operational process; and 2) establish and operate monitoring activities to monitor the internal control system and evaluate results, such as by establishing and operating monitoring activities that are built into each entity's operations, performed continually, and responsive to change.⁵⁶ In addition, federal law directs the agency to develop detailed guidance describing methodologies and options for avoiding duplicate discounts.⁵⁷ Until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance. As a result, manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions.

Audit closure process does not ensure all identified issues of noncompliance are addressed. Under HRSA's audit procedures, covered entities with audit findings are required to 1) submit corrective action plans to HRSA that indicate that the entities will determine the full scope of any noncompliance (beyond the sample of prescriptions reviewed during an audit); 2) outline the steps they plan to take to correct findings of noncompliance, including any necessary repayments to manufacturers; and 3) specify the timelines for implementing the corrective action plans.⁵⁸ HRSA closes the audit when a covered entity

⁵⁶GAO-14-704G.

⁵⁷42 U.S.C. § 256b(d)(2)(B)(iii).

⁵⁸As part of its audit, HRSA reviews a sample of prescriptions filled with 340B drugs during a 6-month period. In the 20 audit files we reviewed, HRSA sampled a total of 1,073 out of 2,286,862 prescriptions (0.05 percent). This included 511 out of 260,839 prescriptions filled at the selected covered entities' contract pharmacies during the audit time frame.

submits a letter attesting that its corrective action plan, including its assessment of the full scope of noncompliance, has been implemented and any necessary repayments to manufacturers have been completed.⁵⁹

However, we identified two specific deficiencies in HRSA's approach. First, although HRSA requires that covered entities determine the full scope of noncompliance found in audits, it does not provide guidance as to how entities should make this assessment. Specifically, HRSA does not specify how far back in time covered entities must look to see if any related noncompliance occurred and instead, relies on each entity to make this determination. For example, a document from a fiscal year 2017 audit revealed that a covered entity that had participated in the 340B Program for 3 years only reviewed 5 months of claims to determine whether any other instances of diversion had occurred, diminishing the likelihood that its efforts identified the full scope of noncompliance. Additionally, until April 2018, HRSA did not require covered entities that were audited to communicate the methodology used to assess the full scope of noncompliance, or the findings of their assessments, including how many or which manufacturers were due repayment. Beginning April 1, 2018, HRSA requires covered entities subject to targeted audits to document their methodology for assessing the full scope of noncompliance. However, as previously noted, only 10 percent of the 200 audits HRSA currently conducts each year are targeted audits. Consequently, the vast majority of covered entities audited are not required to provide HRSA with information on their methodology for assessing the full scope of noncompliance. Furthermore, HRSA officials told us that they believe determining the scope of noncompliance is a matter between the covered entities and manufacturers. Thus, HRSA relies on manufacturers to determine the adequacy of a covered entity's effort to assess the full scope of noncompliance. However, covered entities only contact the manufacturers that they determine were affected by the noncompliance based on the methodology they choose to apply; thus, it is unclear how manufacturers not contacted would be in a position to negotiate an acceptable assessment of the scope of noncompliance and any applicable repayment.

Federal internal control standards related to control activities state that agencies should implement control activities through policies, such as by

⁵⁹Beginning April 1, 2018, HRSA requires covered entities with audit findings to submit a copy of their revised policies and procedures that reflects changes made in response to the audit prior to HRSA closing the audit.

documenting policies in the appropriate level of detail to allow management to effectively monitor the control activity.⁶⁰ As HRSA does not provide guidance on how covered entities are to assess the full scope of noncompliance and does not review most entities' methodology for making such assessments, the agency does not have reasonable assurances that entities have adequately identified all instances of noncompliance.

Second, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity is now in compliance with 340B Program requirements. Beginning April 1, 2018, HRSA requires the 10 percent of covered entities that are subject to targeted audits to provide documentation that they implemented their corrective action plans prior to HRSA closing the audits. However, it still relies on the remaining 90 percent of audited covered entities to self-attest to their compliance with program requirements.

HRSA officials told us they believe that a covered entity providing a description of the corrective actions is sufficient, and that the self-attestation of corrective action plan implementation provides HRSA with the information necessary to close the audit. However, aside from the self-attestation, HRSA's only mechanism to ensure that the majority of audited covered entities have implemented their corrective action plans is to re-audit the entities—in other words, subject the entity to a targeted audit. To date, the agency told us that it has re-audited 21 covered entities, and based on those re-audits, determined that 1 entity did not fully implement its corrective action plan from the original audit. However, we found that of the 19 re-audited covered entities for which results were available, 12 had similar findings of noncompliance in their second audits, as were identified in their original audits (e.g., diversion findings in both audits), 3 of which were caused by the same issue, according to information provided to us by HRSA.

Federal internal control standards for monitoring specify that agencies should establish and operate monitoring activities to monitor the internal control system and evaluate the results, for example by using ongoing monitoring to obtain reasonable assurance of the operating effectiveness of the service organization's internal controls over the assigned process.⁶¹

⁶⁰ [GAO-14-704G](#).

⁶¹ [GAO-14-704G](#).

By only reviewing evidence of corrective action plan implementation for the limited number of covered entities subject to targeted audits, HRSA does not have reasonable assurance that the majority of covered entities audited have corrected the issues identified in the audit, and are not continuing practices that could lead to noncompliance, thus increasing the risk of diversions, duplicate discounts, and other violations of 340B Program requirements.

HRSA's Guidance for Covered Entities' Oversight of Contract Pharmacies Lacks Specificity

HRSA guidance for covered entities on their oversight of contract pharmacies lacks specificity and thus provides entities with considerable discretion on the scope and frequency of their oversight practices. Specifically, HRSA's 2010 guidance on contract pharmacy services specifies that covered entities are responsible for overseeing their contract pharmacies to ensure that drugs the entity distributes through them comply with 340B Program requirements, but states that, "the exact method of ensuring compliance is left up to the covered entity."⁶² The guidance also states that, "annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected," but HRSA officials told us that covered entities are not required to conduct independent audits and instead are expected to do some form of periodic oversight of their contract pharmacies.⁶³ Thus, according to HRSA officials, if a covered entity indicates that it has performed oversight in the 12 months prior to a HRSA audit, then HRSA considers the entity to have met HRSA's standards for conducting contract pharmacy oversight regardless of what the oversight encompassed.

Due, at least in part, to a lack of specific guidance, we found that some covered entities performed minimal contract pharmacy oversight.

- Officials from a grantee reported auditing claims of 5 randomly selected patients quarterly, despite treating approximately 900 patients each month.
- Officials from a critical access hospital that serves about 21,000 patients a year at its outpatient clinics reported that the annual independent audit of their hospital system reviewed five claims.

⁶²75 Fed. Reg. 10278 (Mar. 5, 2010).

⁶³75 Fed. Reg. 10278 (Mar. 5, 2010). HRSA indicated that it does not have statutory authority to require covered entities to conduct annual independent audits of their contract pharmacies.

-
- Officials from two entities reported that they did not contract for an independent audit of their 340B Program, despite HRSA's expectation to do so.

Additionally, of the 20 covered entities whose audits we reviewed, 6 had no documented processes for conducting contract pharmacy oversight.

The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices. Specifically, 66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies, and 33 of the 813 audits for which results were available had findings for lack of contract pharmacy oversight.⁶⁴ However, the number of contract pharmacy oversight findings may be limited by the fact that officials from HRSA's contractor said that its auditors rely on verbal responses from entity officials about any internal review or self-audits conducted by the entity. This is despite the fact that HRSA officials told us that the agency requires auditors to review documentation of covered entities' oversight activities.⁶⁵

Federal internal control standards related to control activities state that agencies should implement control activities through policies, such as by documenting the responsibility for an operational process's objectives and related risks, and control activity design, implementation, and operating effectiveness. The standards also specify that management should periodically review policies, procedures, and related control activities for continued relevance and effectiveness in achieving its objectives or addressing related risks.⁶⁶ As a result of the lack of specific guidance and its numerous audit findings of noncompliance, HRSA does not have assurance that covered entities' contract pharmacy oversight practices are sufficiently detecting 340B noncompliance.

Conclusions

The 340B Program provides covered entities with discounts on outpatient drugs and the ability to generate revenue on drugs purchased under the

⁶⁴These figures are based on the 813 audits conducted by HRSA from fiscal year 2012 to fiscal year 2017 for which results were posted on HRSA's website as of February 8, 2018.

⁶⁵HRSA officials told us that they are updating their policy and protocols to more clearly define HRSA's expectations for its contracted auditor.

⁶⁶[GAO-14-704G](#).

program. Use of contract pharmacies enables covered entities to increase the use of 340B drugs by expanding their distribution networks, thereby increasing the volume of 340B drugs dispensed and generating associated savings and revenue. The expansion of contract pharmacies presents an opportunity for entities to fill more prescriptions with discounted 340B drugs, but it also increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts. Although covered entities and HRSA have taken steps to ensure that 340B Program requirements are being met at contract pharmacies, HRSA's audits continue to identify instances of noncompliance.

As currently structured, weaknesses in HRSA's oversight impede its ability to ensure compliance with 340B Program requirements at contract pharmacies. HRSA cannot ensure that its limited number of audits target covered entities with the most complex 340B programs, and thus the greatest risk of noncompliance, because the agency does not have complete data on entities' contract pharmacy arrangements. Additionally, HRSA's audit process does not adequately identify compliance issues, nor does it ensure that identified issues are corrected. HRSA's audits do not assess compliance with a key 340B Program requirement (the prohibition regarding duplicate discounts) as it relates to Medicaid managed care, and HRSA does not provide audited entities with guidance for determining the full scope of noncompliance, which reduces the effectiveness of HRSA's audits in identifying drug diversion and duplicate discounts. Moreover, where audits identify instances of noncompliance, HRSA's process does not confirm that all covered entities successfully correct the deficiencies and take steps to prevent future noncompliance. Although HRSA made improvements to its process for targeted audits during the course of our review, the agency does not require most covered entities subject to an audit to provide evidence of corrective actions taken.

Moreover, the lack of specificity in HRSA's guidance to covered entities on the methods through which they should ensure compliance may impede the effectiveness of entities' oversight. For example, without guidance instructing covered entities how to prevent duplicate discounts in Medicaid managed care, entities are left to individually navigate the policies and practices of states and private insurers. Furthermore, by not clearly communicating expectations for covered entities' oversight of their contract pharmacies, HRSA faces the risk that instances of noncompliance, such as diversion, at contract pharmacies will not be identified and addressed. As the 340B Program continues to grow, it is essential that HRSA address these shortcomings.

Recommendations for Executive Action

We are making the following seven recommendations to HRSA:

- The Administrator of HRSA should require covered entities to register contract pharmacies for each site of the entity for which a contract exists. (Recommendation 1)
- The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs. (Recommendation 2)
- The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities. (Recommendation 3)
- The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit. (Recommendation 4)
- The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance. (Recommendation 5)
- The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit. (Recommendation 6)
- The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight. (Recommendation 7)

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reproduced in app. II, and technical comments, which we have incorporated as appropriate. In its written comments, HHS concurred with four of our seven recommendations, did not concur with three of our

recommendations, and stated that it had concerns with some of the other information in our report.

In concurring with four of our recommendations, HHS stated that HRSA is making changes to its audit process to strengthen oversight of the 340B Program. Regarding our recommendation related to guidance on duplicate discounts, HHS concurred, but commented that the recommendation did not account for the critical role that CMS would play in its successful implementation. We agree that CMS would play an important role in ensuring compliance with the prohibition on duplicate discounts in Medicaid managed care, which is why we recommended that HRSA coordinate with CMS on the guidance. HHS indicated that HRSA and CMS are strategizing on effective ways to address this issue. HHS also concurred with our recommendations to issue guidance related to identifying the full scope of noncompliance and covered entities' oversight of their contract pharmacies, although it noted that HRSA would face challenges in issuing guidance related to areas where it does not have explicit regulatory authority. While we recognize that HRSA's authority to issue regulations governing the 340B Program may be limited, our recommendations were focused on HRSA clarifying certain program requirements through whatever format the agency deems appropriate. Since the establishment of the 340B Program, HRSA has used interpretative guidance and statements of policy to provide guidance to covered entities regarding compliance with program requirements. HRSA has also used certain of its audit procedures, such as the template provided to covered entities for the development of corrective action plans, to provide such clarifications. Our recommendations are intended to expand the availability of information HRSA provides to covered entities to help them improve compliance with existing program requirements. As such, we continue to believe that further clarification, whether provided as interpretive guidance, audit procedures, or another format, is necessary to help ensure compliance with program requirements.

Among the recommendations with which HHS did not concur was our recommendation to require covered entities to register contract pharmacies for each site of the entity for which a contract exists. HHS stated that its current registration process is responsive to our concerns for all covered entity types other than hospitals and health centers. However, as we note in the report, hospitals and FQHCs are typically the covered entity types that have multiple sites, and are generally more likely to have contract pharmacies. HHS cited administrative burden for both covered entities and HRSA as a reason not to require covered entities to

provide more complete information about contract pharmacy arrangements. However, given that HRSA requires covered entities to register both their sites and their contract pharmacies with the agency, it is unclear why there would be significant additional burden for covered entities to indicate which of the previously registered sites had contracts with which contract pharmacies. It is also important to note that contract pharmacy use by covered entities is voluntary, and covered entities that choose to have contract pharmacies are required to oversee those pharmacies to ensure compliance with 340B Program requirements. Therefore, the use of contract pharmacies inherently comes with additional administrative responsibilities for the covered entity, and we believe that the requirement to register each contract pharmacy arrangement with HRSA should present limited additional burden on covered entities.

Rather than implementing our recommendation, HHS stated that HRSA will make changes to its audit selection process; HRSA will assume that all contract pharmacies registered with the parent site would also be used by all sites of the covered entity prior to selecting entities for risk-based audits. Although this may be a good step forward, it does not provide information on the actual number of contract pharmacy arrangements for each covered entity. As such, we continue to believe that HRSA needs more complete information on contract pharmacy arrangements to best target its limited number of audits to covered entities with the most complex 340B programs. This is also important information to provide manufacturers to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site.

HHS also did not concur with our two recommendations to require covered entities to specify their methodologies for identifying the full scope of noncompliance identified during their audits as part of their corrective action plans, and to provide evidence that these plans have been successfully implemented prior to HRSA closing audits. In its response, HHS noted that on April 1, 2018, HRSA implemented these requirements for entities subject to targeted audits (including re-audits), which represent 10 percent of all entities audited. However, HRSA indicated that implementing these requirements for all covered entities that are audited would create a significant burden for these entities. As we previously noted, HRSA already requires covered entities with audit findings to determine the full scope of noncompliance and to submit corrective action plans. Thus, it is unclear how requiring covered entities to include written descriptions of their methodologies for identifying the full

scope of noncompliance, which should already be formulated, and to provide evidence that the corrective actions that entities developed have been implemented, would create significant additional burden for these entities.

HHS also expressed concern that these additional steps would significantly delay the audit process and repayments to manufacturers. We recognize that reviewing these documents may create some additional work for HRSA and possibly require additional time to close audits. However, we believe this additional work and time is necessary for the audits to be effective at adequately identifying compliance issues and ensuring that those issues are corrected. Furthermore, these additional actions could reduce the need for re-audits which are burdensome in terms of cost and time, for both the covered entity and HRSA.

Finally, HHS also expressed concerns about some of the other information included in the draft report.

- HHS stated that disclosing actual fees paid by covered entities to pharmacies and TPAs could cause disruptions in the drug pricing market and fluctuations in fees entities pay. Our report provides fees for a small and nongeneralizable sample of contracts, covered entities, and TPAs. For example, we provide contract pharmacy fees for 30 of the thousands of contracts that exist between covered entities and pharmacies. It is unclear how this information could cause disruptions in the drug pricing market or lead to fluctuations in fees covered entities may pay, and HHS did not provide any evidence to support its assertion. Additionally, HHS has raised questions about the effect of the 340B Program on drug pricing.⁶⁷ As such, we believe that our discussion of fees brings enhanced transparency to the 340B Program, and provides Congress with important information it requested to gain a better understanding of the program and enhance its oversight.
- Regarding the distance between contract pharmacies and covered entities, HHS noted that the longest distance was for a specialty pharmacy that was registered for 17 days. As noted in our scope and methodology, our analysis was of covered entities and contract pharmacies participating as of July 1, 2017. Additionally, there were

⁶⁷Department of Health and Human Services, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, (Washington, D.C.: May 2018).

other contract pharmacy arrangements of similarly long distances. HHS also expressed concern that the draft report did not note that such specialty pharmacies may be needed due to restricted distribution by a manufacturer, which would be outside a covered entity's control. In our report, we noted that the 340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away. However, the report does include some potential reasons HRSA provided us as to why this may occur.

- HHS also commented that our table on the number and percent of covered entities audited does not fully reflect HRSA's auditing efforts because it does not include the number of entity sites and contract pharmacies included within each audit. However, HRSA's audits of covered entities generally do not include visits to multiple covered entity sites, or all contract pharmacies that distribute 340B drugs on a covered entity's behalf. Additionally, while the audits include a review of a sample of 340B drugs distributed, that sample may not include prescriptions written at, or dispensed from, all of the covered entity's sites or contract pharmacies. As a result, information in our report highlights the number of entities that were audited.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Administrator of HRSA, and other interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at DraperD@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix III.



Debra A. Draper
Director, Health Care

Appendix I: Summary of Fees Included in 340B Pharmacy Contracts Reviewed

Table 8 provides a brief description of the fees that covered entities pay pharmacies with which they contracted to dispense 340B drugs based on our review of 30 contracts.

Table 8: Fees That 30 Selected Covered Entities Pay to Contract Pharmacies for Dispensing 340B Drugs, by Entity Type

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Hospitals		
Critical access hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$24 for each brand drug prescription Flat fee of \$15 for each prescription patient pays with cash Generic drugs excluded
Critical access hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$15 for each prescription
Critical access hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$28 for each brand drug prescription for patients with insurance coverage Limited to brand drugs
Critical access hospital	Independent	<ul style="list-style-type: none"> Flat fee of \$17 for each prescription
Critical access hospital	Independent	<ul style="list-style-type: none"> Flat fee of \$15 for each prescription
Critical access hospital	Not available ^a	<ul style="list-style-type: none"> Flat fee of \$24 for each brand drug prescription Generic drugs excluded
Critical access hospital	Not available ^a	<ul style="list-style-type: none"> Fee of \$0 for each prescription
Disproportionate share hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$15 for each prescription when patient has insurance coverage Up to 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$15 for each prescription when patient has insurance coverage Up to 15 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$15 for each prescription when patient has insurance coverage 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments The covered entity does not pay any fees if the patient does not have insurance coverage

**Appendix I: Summary of Fees Included in 340B
Pharmacy Contracts Reviewed**

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Disproportionate share hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$15 for each prescription when patient has insurance coverage 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$18 for each generic drug prescription Flat fee of \$25 for each brand drug prescription
Disproportionate share hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$30 for each brand drug prescription
Disproportionate share hospital	Chain	<ul style="list-style-type: none"> Flat fee of \$22 for each brand and generic drug prescription
Disproportionate share hospital	Independent	<ul style="list-style-type: none"> Flat fee of \$5 for each generic drug prescription Flat fee of \$10 for each brand drug prescription
Federal grantees		
Federally qualified health center	Chain	<ul style="list-style-type: none"> Flat fee of \$28 for each brand drug prescription for patients using a drug discount card^b or insurance Limited to brand drugs
Federally qualified health center	Chain	<ul style="list-style-type: none"> Flat fee of \$6 for each brand and generic prescription for patients using a drug discount card^b Flat fee of \$7 for each brand and generic prescription when patient has insurance coverage 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Federally qualified health center	Chain	<ul style="list-style-type: none"> Flat fee of \$6 for each brand and generic prescription for patients using a drug discount card^b Flat fee of \$7 for each brand and generic prescription when patient has insurance coverage 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Federally qualified health center	Chain	<ul style="list-style-type: none"> Flat fee of \$8 for each brand prescription for patients using a drug discount card^b Flat fee of \$24 for each brand prescription when patient has insurance coverage
Federally qualified health center	Chain	<ul style="list-style-type: none"> Flat fee of \$8 for each brand and generic prescription for patients using a drug discount card^b Flat fee of \$9 for each brand and generic prescription when patient has insurance coverage 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug

**Appendix I: Summary of Fees Included in 340B
Pharmacy Contracts Reviewed**

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Federally qualified health center	Independent	<ul style="list-style-type: none"> Flat fee of \$8 for each brand and generic prescription for patients using a drug discount card^b Flat fee of \$10 for each prescription when patient has insurance coverage 14 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments
Federally qualified health center	Independent	<ul style="list-style-type: none"> Flat fee of \$6 for each brand and generic prescription for patients using a drug discount card^b Flat fee of \$7 for each brand and generic prescription when patient has insurance coverage 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Other federal grantee	Alternate dispensing site ^c	<ul style="list-style-type: none"> Flat fee of \$0.06 per international unit of factor^d
Other federal grantee	Chain	<ul style="list-style-type: none"> Flat fee of \$13 for each prescription when patient has insurance coverage Up to 18 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Chain	<ul style="list-style-type: none"> Flat fee of \$0.09 per international unit of factor^d
Other federal grantee	Chain	<ul style="list-style-type: none"> Flat fee of \$13.50 for each prescription when patient has insurance coverage Up to 13 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Chain	<ul style="list-style-type: none"> Flat fee of \$13 or \$65 (for specialty drugs) for each prescription when patient has insurance coverage 13 percent, or up to 13 percent (for specialty drugs), of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Independent	<ul style="list-style-type: none"> Flat fee of \$3 for each prescription
Other federal grantee	Independent	<ul style="list-style-type: none"> Flat fee of \$125 for each brand and generic human immunodeficiency virus drug Flat fee of \$1,750 for each brand Hepatitis C drug Fee of \$0 for each generic Hepatitis C drug Flat fee of \$75 for each brand and \$0 for each generic drug not included above

**Appendix I: Summary of Fees Included in 340B
Pharmacy Contracts Reviewed**

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Other federal grantee	Not available ^a	<ul style="list-style-type: none"> Flat fee of \$10 for each prescription when patient does not have insurance coverage Flat fee of either \$10 when patient has insurance coverage or 12 percent of the of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments, whichever is greater

Source: GAO review of selected 340B contracts and DataQ data. | GAO-18-480

Note: Information on pharmacy type comes from the National Council for Prescription Drug Programs' DataQ, a database containing information reported by pharmacies that is used by health care payers and claims processors across the country to identify pharmacies.

^aFor these pharmacies information was not available in DataQ on pharmacy type.

^bSome covered entities provide their patients with a drug discount card that the patient can present at the contract pharmacy. The pharmacy then uses the discount card to verify the patient as 340B eligible and determine the amount the patient will pay for the prescription.

^cAn alternate dispensing site is a pharmacy or dispensing site such as a physician's office or emergency department.

^dFactor refers to blood clotting factor, which is the main treatment used for hemophilia—a bleeding disorder in which the blood does not clot normally. Patients with hemophilia are provided with infusions of blood clotting factor containing a protein to aid in clotting.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 04 2018

Debra Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*" (GAO-18-480).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. D. Bassett for".

Matthew D. Bassett
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

HHS places the highest priority on the integrity of the 340B Program and continually works to strengthen oversight of the Program, including ongoing improvement of its audit process. HHS appreciates GAO's examination of 340B covered entities use of contract pharmacies. During the course of the study, HRSA took the opportunity to make improvements to the program and has already implemented some of GAO's recommendations. While GAO's work will continue to inform our program integrity efforts, implementing some of the other recommendations in this report are not feasible at this time; they would require significant resources, currently not available under the Program's funding authorities. Successful implementation would require significant expansion of the Program's current information technology systems to account for new audit functions as well as strengthened enforcement authority and additional staff to oversee these efforts. In addition, HHS notes that some of the recommendations would impose additional audit requirements—and by extension, significant burden—on covered entities, especially smaller entities who are often resource constrained.

HHS also has significant concerns regarding many of the findings in the draft report. While discussion of the fees that covered entities pay their contract pharmacies and third party administrators (TPA) to dispense 340B drugs is within scope of the study's objectives, disclosing the actual fees, which are not widely available, could cause disruptions in the drug pricing market and lead to fluctuations in the fees that covered entities are charged. Further, it is important to note that HRSA has no legal authority to address the fees that a contract pharmacy or TPA may charge a covered entity for dispensing drugs to patients of the entity, as the fees are a private business matter between the parties involved. Covered entities utilize contract pharmacies and TPAs as an access point for patients to obtain 340B drugs. Without an explicit statement that HRSA lacks statutory authority to address these fees, the reader could be led to believe that fees are within the purview of the Program.

In addition, the GAO found in its analysis that the distance between a covered entity and its contract pharmacies was measured from the pharmacy to the closest site of the entity and that mail order pharmacies were excluded from distance calculations. GAO also explains that the maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut contracting with a specialty pharmacy in Hawaii. Important context missing from GAO's report is the rationale for why a specialty pharmacy may be needed in the first place—such as the case of restricted distribution by a manufacturer, which would be outside a covered entity's control. HRSA also notes that the hospital in Connecticut that contracted with a specialty pharmacy in Hawaii was registered for 17 days and the pharmacy contract was subsequently terminated by the covered entity on July 17, 2017.

GAO's analysis was also not fully reflective of HRSA's auditing efforts which was a central objective of the study. "Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), by Fiscal Year," lists the number of audits by fiscal year and the percent of covered entities audited. While the numbers are accurate,

Page 1 of 6

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

it does not fully capture the significant number of sites included within each audit. HRSA notes the total number of audited sites below to provide the reader with the full scope of HRSA's oversight efforts.

- FY 12 – 51 audits, 410 outpatient/sub-grantee sites, 860 contract pharmacies
- FY 13 – 94 audits, 718 outpatient/sub-grantee sites, 1937 contract pharmacies
- FY 14 – 99 audits, 1476 outpatient/sub-grantee sites, 4028 contract pharmacies
- FY 15 – 200 audits, 2720 outpatient/sub-grantee sites, 4443 contract pharmacies
- FY 16 – 200 audits, 4011 outpatient/sub-grantee sites, 3531 contract pharmacies
- FY 17 – 200 audits, 2046 outpatient/sub-grantee sites, 4052 contract pharmacies

Finally, GAO makes several recommendations directing HRSA to issue guidance on specific policy matters. While HHS appreciates the recommendations to issue guidance, we would face challenges with issuing guidance on 340B policy matters in cases where our enforcement authority is quite limited. HHS notes that HRSA currently lacks explicit general regulatory authority in the 340B statute to issue regulations on most aspects of the 340B Program. Exceptions to this include the calculation of the ceiling price, manufacturer civil monetary penalties, and administrative dispute resolution. A regulation is a binding, enforceable document that would dictate specific 340B Program requirements and provide the clarity necessary for stakeholders to be fully compliant. HHS notes that the 2011 GAO report also included a recommendation related to hospital eligibility; however, HRSA remains unable to address the report's two recommendations without legislative changes, including the expansion of regulatory authority.

HHS notes that the FY 2019 President's Budget includes a proposal to amend the 340B statute to provide HRSA explicit general regulatory authority. If this proposal were enacted by Congress, HRSA could conduct rulemaking for all provisions in the 340B statute, affording it explicit, general regulatory authority, which would be most effective in facilitating HRSA's oversight over the 340B Program. In addition, explicit general regulatory authority would allow HRSA to provide greater clarity and specificity to Program requirements necessary for implementing GAO's 2011 recommendations and the recommendation in this report.

HRSA continues to support the development of program policy as a general matter and is working with the Administration to determine next steps on several aspects of Program policy.

Recommendation 1

The Administrator of the Health Resources and Services Administration (HRSA) should require covered entities to register contract pharmacies for each site of the entity for which a contract exists.

HHS Response

HHS non-concurs with GAO's recommendation.

- HRSA notes that its current process is already responsive to GAO's recommendation for covered entity types other than hospitals and health centers. Because HRSA recognizes

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

relationships of hospitals and health centers in a different manner (parent and child), and for administrative burden reasons, HRSA only requires that a contract pharmacy register with the parent covered entity, notwithstanding that child sites can still utilize that pharmacy. HRSA does require all covered entity sites and contract pharmacy sites to be listed on the written contract, and this information is audited by HRSA.

- For the FY 2019 audit cycle, HRSA will strengthen this risk-based audit strategy by including an assumption that all contract pharmacies registered with the parent entity would also be used by the child sites, prior to randomly selecting covered entities for audit. Adding this assumption to the methodology, rather than requiring registration for all contract pharmacy contracts, will preclude having to strain HRSA's IT system and, more importantly, it will avoid placing significant burden on covered entities that only list their contract pharmacy with the parent organization.
- GAO explains that because HRSA allows covered entities to utilize multiple contract pharmacy registration options, the likelihood of being selected for an audit is dependent on how an entity registers its pharmacies. HRSA does not believe that requiring entities to register each contract pharmacy in the database is the appropriate mechanism to address the GAO's specific concern. In assessing the scope and effectiveness of implementing this proposed recommendation, HRSA conducted an internal analysis in line with GAO's scenario where all contract pharmacies listed under the parent entity (for hospitals and health centers) are also listed under all of their child sites. HRSA concludes that its existing risk-based selection method is effective and efficient in selecting covered entities with the most contract pharmacy arrangements.

Recommendation 2

The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS, as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs.

HHS Response

HHS concurs with GAO's recommendation.

- While HRSA recognizes the need for guidance, GAO's recommendation as currently stated does not account for the critical role that CMS would play in its successful implementation. Development of effective and comprehensive guidance would require that HRSA and CMS work closely together under the guidance of departmental leadership. In this regard, HRSA continues to hold calls with CMS and discuss concerns and strategize on effective ways to address the issue for both the Medicaid and 340B Program.

Recommendation 3

The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

HHS Response

HHS concurs with GAO's recommendation.

- HRSA notes that this recommendation can only be accomplished after guidance has been issued as outlined in recommendation 2.
- While HRSA does not currently audit Medicaid managed care claims and has no policy on preventing duplicate discounts in this context, we encourage covered entities and manufacturers to work on strategies to ensure compliance with the duplicate discount prohibition. After reviewing our policy in this area, beginning April 1, 2018, HRSA now includes an area for improvement (AFI) in audits where Medicaid managed care claims are identified as potential risks. Further, HRSA has since updated its policy on April 1, 2018 to add that all entities with findings are required to provide information regarding their plan to implement any areas for improvement.

Recommendation 4

The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit.

HHS Response

HHS concurs with GAO's recommendation.

- The ability for HRSA to issue guidance is predicated on the challenges of issuing guidance versus regulations that are discussed above. HRSA supports the development of program policy and is working with the Administration to determine next steps.

Recommendation 5

The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance.

HHS Response

HHS non-concurs with GAO's recommendation.

- As indicated by the GAO in the draft report (page 35), beginning April 1, 2018, HRSA requires entities that are subject to target audits and re-audits to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of non-compliance.
- Covered entities must work in good faith with manufacturers to remedy any repayment owed after the entity determines the compliance. Covered entities and manufacturers have

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

access to the necessary data needed to resolve any repayment, which is a private matter between the two parties due to their established business relationship.

- HRSA notes that if this recommendation were implemented for all audits, it would create a significant burden for covered entities to comply with the additional documentation they would need to produce as part of the audit. In addition, the timeframe it would take HRSA to review GAO's recommended methodology for identifying the full scope of noncompliance and to close an audit would be significantly extended.
- HRSA has established an efficient audit process to ensure that if there is a compliance issue, particularly involving repayment to a manufacturer, covered entities are able to resolve the issue quickly and notify the manufacturer in order to work out repayments that may be owed in good faith. Additional requirements related to document submission will significantly delay the process and repayment to manufacturers due to program violations.

Recommendation 6

The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessment of the full scope of noncompliance identified during an audit.

HHS Response

HHS non-concurs with GAO's recommendation.

- For all audits, HRSA requires covered entities to describe in detail their plan for corrective action. If during the course of review of the CAP concerns arise, HRSA would request additional documentation that would describe the steps taken to correct any noncompliance. As indicated by the GAO in the draft report (page 35), beginning April 1, 2018, HRSA took additional action to require evidence and documentation as outlined in the recommendation for entities that are subject to target audits and re-audits.
- Requiring all entities to provide evidence and documentation as outlined in the recommendation, would create a significant burden for covered entities to comply with the additional materials they would need to produce as part of the audit.
- In addition, the timeframe it would take HRSA to review GAO's recommended methodology for identifying the full scope of noncompliance and to close an audit would be extended. HRSA has established an efficient audit process to ensure that if there is a compliance issue, particularly involving repayment to a manufacturer, covered entities are able to resolve the issue quickly and notify the manufacturer in order to work out repayments that may be owed in good faith. Additional requirements related to document submission will delay the audit process significantly, thus delaying repayment to affected manufacturers due to program violations.

Recommendation 7

The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT
REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF
COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-
18-480)**

HHS Response

HHS concurs with GAO's recommendation.

- HRSA's ability to issue guidance is predicated on the challenges with issuing guidance versus regulations discussed above. HRSA supports the development of program policy and is working with the Administration to determine next steps.

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contact

Debra A. Draper (202) 512-7114 or DraperD@gao.gov

Acknowledgments

In addition to the contact named above, Michelle Rosenberg (Assistant Director), N. Rotimi Adebajo (Analyst in Charge), Jennie Apter, George Bogart, Amanda Cherrin, David Lichtenfeld and Dan Ries made key contributions to this report. Also contributing were Julianne Flowers and Vikki Porter.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<https://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <https://www.gao.gov> and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <https://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [Twitter](#), and [YouTube](#).
Subscribe to our [RSS Feeds](#) or [E-mail Updates](#). Listen to our [Podcasts](#).
Visit GAO on the web at <https://www.gao.gov>.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Website: <https://www.gao.gov/fraudnet/fraudnet.htm>

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Orice Williams Brown, Managing Director, WilliamsO@gao.gov, (202) 512-4400,
U.S. Government Accountability Office, 441 G Street NW, Room 7125,
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548

Strategic Planning and External Liaison

James-Christian Blockwood, Managing Director, spel@gao.gov, (202) 512-4707
U.S. Government Accountability Office, 441 G Street NW, Room 7814,
Washington, DC 20548



Please Print on Recycled Paper.